A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS

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DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled **"A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS"** submitted towards partial fulfillment of the requirements for the award of **MD IN ANAESTHESIOLOGY** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Namrata,** Former Associate Professor, Department of Anaesthesiology, **Dr. Mirley Rupinder Singh,** Professor, Department of Anaesthesiology, & **Dr. Seema Gupta,** Associate Professor, Department of Anatomy, DMCH. No part of this thesis has formed the basis for the award of any degree previously.

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LIST OF ABBREVIATIONS

%	Percentage
ASA	American society of anaesthesiologist
cm	Centimetre
CO_2	Carbon dioxide
ECG	Electrocardiography
$ETCO_2$	End tidal carbon dioxide
ETT	Endotracheal tube
FOB	Flexible fibreoptic bronchoscope
H_2O	Water
IOP	Intraocular pressure
kg	Kilogram
LMA	Laryngeal mask airway
mcg	Microgram
mg	Milligram
Min	Minutes
ml	Millilitres
mmHg	Millimetres of mercury
NIBP	Non invasive blood pressure
NRS	Numerical rating scale
OLP	Oropharyngeal leak pressure
PCV	Pressure control ventilation
PEEP	Positive end expiratory pressure
PLMA	Proseal laryngeal mask airway
PVC	Polyvinyl chloride
SAD	Supraglottic airway device
SD	Standard deviation
SpO_2	Arterial oxyhemoglobin saturation
TV	Tidal volume
V/Q	Ventilation/perfusion
VC	Vital capacity

ABSTRACT

Introduction: Ambu Auragain laryngeal mask airway (LMA) has been used in patients for short to medium duration surgical procedures and has proved to be beneficial. Appropriate size selection of the LMA has contributed to its successful placement in the first attempt, thereby avoiding multiple episodes of desaturation and other associated respiratory or hemodynamic complications. We hypothesized that the auricle size based method of size determination of LMA would be better in comparison to the weight based method.

Aim of Study: To compare the successful placement of Ambu AuraGain LMA in the first attempt using auricle size based method and weight based method in adult population.

Materials & methods: A prospective, randomized, interventional trial was conducted on 120 ASA I, II and III adult patients undergoing surgical procedures under general anaesthesia, divided into 2 groups. In group A, AuraGain LMA size was selected based on the size of the auricle of the patient while in group B, AuraGain LMA size was selected based on weight of the patient. Successful placement of AuraGain LMA, time taken for insertion, number of attempts for successful insertion, intra-operative and post-operative complications were studied. Data collected was statistically analysed.

Results: The mean oropharyngeal leak pressure (24.60+-2.53 versus 30.53+-1.80 cmH_2O, p-value 0.001) and the mean time of insertion (14.05+-1.97 versus 16.12+-2.50 secs) were statistically significant. The OLP was favourable for group B and insertion time for group A. Post-operative complications were more in group B as compared to group A.

Conclusion: The determination of size of LMA by auricle size based method had easier insertion as compared to the weight based method. The incidence of post-operative complications were also lower in the auricle size group. However the airway seal pressures were higher in the weight based group making it better for positive pressure ventilation.

Keywords: Auragain LMA, Weight, Auricle size, Oral leak pressure

Dedicated

to

my family

&

Teachers

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COMMIT TO THE LORD WHATEVER YOU DO, AND HE WILL ESTABLISH YOUR PLANS. Successful completion of a task is often less due to individual talent than to the fact that the person has been blessed by the 'GOD ALMIGHTY'.

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INTRODUCTION

General anaesthesia allows complex surgical and diagnostic procedures in patients of all age groups even in critically ill patients. Administering general anaesthesia results in loss of normal airway reflexes, hence the need to secure the airway becomes necessary.[1,2]

Endotracheal intubation is the preferred modality during general anaesthesia as it provides a definitive airway. The tracheal tube cuff provides the laryngeal seal thus preventing risk of aspiration of gastric contents. Moreover with endotracheal tubes the inflation pressures are higher to provide positive end expiratory pressures (PEEP) and vital capacity (VC) manoeuvres thus preventing atelectasis.[1,3]

Although endotracheal intubation is routinely used for securing the airway, it is associated with increased hemodynamic stress response due to laryngoscopy and intubation. Also multiple attempts at laryngoscopy and intubation are associated with higher incidence of hoarseness, sore throat and dysphagia.[4] Use of muscle relaxants causes increase in V/Q mismatch resulting in atelectasis.[3]

Laryngeal mask airways (LMA) are replacing endotracheal intubation during general anaesthesia or act as a bridge between endotracheal intubation and bag and mask ventilation in case of emergency or difficult airway management. They play an important role in maintaining ventilation and providing oxygenation to the patients.[5,6]

Supraglottic airway devices (SAD) are gaining popularity because of their ease of insertion and higher successful rate of insertion at first attempt, thus reducing number of episodes of desaturation and lesser hemodynamic stress response to laryngoscopy. The incidence of sore throat and dysphagia has also been lower in supraglottic airway devices. The insertion of supraglottic airway devices does not mandate the use of muscle relaxants, thus reducing atelectasis and providing better respiratory outcomes.[1,3,4] Many studies are in favour of the supraglottic

airway devices in terms of safety profile, complication risk, ease of insertion, recovery of patients and cost analyses.[7]

Despite various advantages offered by SADs, there is increased risk of aspiration, inadequate insertion, suboptimal ventilation, bronchospasm and laryngospasm.[7] To overcome these complications, second generation SADs are provided with gastric drain tube to allow efflux of gastric contents.[1]

Oropharyngeal leak pressure (OLP) is a marker of safety and efficacy of supraglaottic airway devices. A higher OLP corresponds to better seal between the supraglottic airway devices and the underlying mucosa. This allows for positive pressure ventilation and protection against gastric aspiration. Newer supraglottic airway devices are designed to achieve higher OLPs, increased gastric venting and allows SAD-guided intubations. Higher OLPs are required in obese patients, increased intra-abdominal pressure in laproscopic surgeries and in patients with restrictive lung diseases.[8]

The Ambu AuraGain, a second generation laryngeal mask airway, is used for both ventilation as well as a conduit for tracheal intubation. It is a single use SAD and is made of polyvinyl chloride (PVC). It has gastric access, bite block and wide airway tube. It has its original anatomical curve which helps in rapid placement. It also has a thin and soft cuff which helps in providing a good seal thus preventing gastric regurgitation and aspiration.[9]

There have been many studies comparing Ambu AuraGain with other second generation SADs showing that Ambu AuraGain has better oropharyngeal seal pressure and easier gastric tube insertion making it more suitable for use with positive pressure ventilation. This allows for increased margin of safety with regards to risk of aspiration. The insertion time of Ambu AuraGain is shorter as compared to many SADs such as LMA Proseal.[8,9] It has also shown better performance in children as compared to LMA Supreme as more airway manoeuvres are required in the later to maintain a patent airway.[10] Ambu AuraGain

makes endotracheal tube insertion quicker and easier compared to LMA fastrack when used as a conduit.[11] In various studies, Ambu AuraGain is considered better than endotracheal intubation in terms of ease in use, lesser fluctuations in hemodynamic responses and perioperative complications.[12]

Selection of proper size of LMA is important for its safe and effective use. The weight based technique, which is the gold standard method is not always accurate. The size of the airway anatomy does not relate linearly to the body weight such as in obese and malnourished patients. The patient's weight is sometimes not known such as in immobilised and unconscious patients or medical personnel do not remember the relationship between patient's weight and appropriate size of the LMA. These factors may lead to inappropriate size selection with larger size LMA causing airway trauma and a smaller one causing inadequate ventilation.[13]

Thus it is essential to have an alternate method to determine the size of laryngeal mask airway. This method should be accurate in determining the size of laryngeal mask airway, easy to perform, easy to remember and can be used at patient's bedside.[13]

To overcome these concerns various alternatives to weight based technique have been tried by researchers. Meilin Weng et al in a study concluded that thyromental distance is better than weight based method to determine the size of LMA in terms of better ventilation, easier placement and reliable pharyngeal seal.[14] Yi-Hsuan Huang et al proposed that tongue width based method is a convenient alternative to weight based method for selecting optimal size LMA.[15] Gallart et al proposed 3 finger sizing method to determine the size of LMA after conducting a study on 183 children.[13] Zahoor et al in 2012 studied the use of external ear as a surrogate marker to determine the correct size of LMA in 210 pediatric patients.[16] They found the ear size based method to be comparable to that of weight based method. Both the above studies were restricted only to pediatric population. There have

been very limited studies to determine the accurate size of LMA in adult population.

Since the shape and size of the auricle corresponds to that of the LMA, we hypothesized that the auricle size based technique would be comparable to weight based technique for selection of appropriate size LMA in adult population. The scientific studies to compare the two techniques are in pediatric age group, we proposed to compare these techniques in adult population in terms of successful placement at first attempt, oral leak pressures (OLP), change of size of LMA required, episodes of intra-operative desaturation and post operative complications if any.

AIMS AND OBJECTIVE

To compare the successful placement of LMA in the first attempt using auricle size based method and weight based method in adult population.

REVIEW OF LITERATURE

Supraglottic airway devices (SADs) are group of airway devices that are inserted into the pharynx to provide oxygenation, ventilation and administration of anaesthetic gases without intubation of trachea.[17] SADs are now widely used for airway management and for maintenance of anaesthesia. They can be used for oxygenation and as conduits for tracheal tube insertion in cases of difficult or failed intubation. They also serve as rescue devices in situations of difficult oxygenation with facemask. Newer devices can also be used in laproscopic procedures as well as in obese patients without increased risk for aspiration of gastric contents due to presence of gastric port.[8,18]

Supraglottic airway devices such as laryngeal mask airway(LMA) are mostly used in the operating room whereas devices such as combitube, laryngeal tube and pharyngeal tube are commonly used in the emergency department and for prehospital airway management.[17]

Laryngeal mask airway maintains haemodynamic and respiratory stability of the patients, better mucociliary clearance with reduced need for anaesthetics. It reduces the risk of traumatisation of glottic structures. It lowers the incidence of post operative complications such as laryngospasm, hoarseness, sore throat and nausea as compared to the use of an endotracheal tube(ETT).[19,20] Zoremba M et al conducted a study on 134 patients to compare intubation and Proseal LMA in moderately obese adults posted for short to medium duration surgeries. They aimed to evaluate the postoperative lung volumes and arterial oxygen saturation in early postoperative period after intubation and LMA use. They also compared endotracheal intubation with SAD on parameters like leak pressure, ease of intubation and urgency to secure airway. They concluded that LMA confers advantage for moderately obese adults in terms of early recovery of post-operative lung functions and can be used as an alternative to endotracheal intubation in short surgeries.[3]

Cochrane systematic review compared studies on use of Proseal LMA and endotracheal tube in obese patients. They concluded that although Proseal LMA takes longer time to insert, but once fitted properly it provide as good oxygenation as endotracheal intubation. They also found significant improvement in oxygenation intra-operatively and post-operatively and reduced complications such as coughing, sore throat, hoarseness, etc after the surgery with the use of Proseal LMA.[21]

Ulku Sabuncu et al conducted a study on 114 ASA I-II patients and compared Ambu AuraGain and I-gel with endotracheal intubation for airway control during general anaesthesia in laproscopic surgeries in terms of ease of application and perioperative complications. Hemodynamic responses are lesser seen in Ambu AuraGain considering them in a better place than endotracheal intubation.[12]

Uppal V et al compared cuffed endotracheal tube with I-gel in 20 patients during positive controlled ventilation (PCV) and found that there was no significant difference in the leak fractions at 15-20 cm H2O. There was no gastric insufflations with I-gel at any pressure. It was concluded that I-gel can be used as an alternative to tracheal intubation during PCV.[22]
Lai CJ et al conducted a study in 40 patients undergoing laproscopic pneumoperitoneum surgeries and found that I-gel had significantly lower resistance and higher compliance and produced similar leak fractions, leak volumes and airway pressures as in ETT. They concluded that I-gel is a suitable alternative to ETT in laproscopic pneumoperitoneum and trendelenberg position.[23]

Priyanka Dwivedi et al conducted a study on 45 pediatric patients from 1-12 years of age undergoing elective non-ocular surgeries under general anaesthesia. These patients were randomly and equally divided into 3 groups and their airways were secured by endotracheal tube, Ambu AuraGain and I-gel in the respective groups. The study was aimed at measuring and comparing intraocular pressure (IOP) changes of both eyes at pre-defined intervals. They found that endotracheal intubation caused significant increase in IOP as compared to Ambu AuraGain and

I-gel. Thus they concluded that Ambu AuraGain and I-gel are better than endotracheal tube in the pediatric patients.[24]

Metus Oterkus et al studied 69 ASA I-II patients aged 18-60 years undergoing septoplasty. They compared Ambu AuraGain with endotracheal intubation in terms of hemodynamic and respiratory parameters and concluded that Ambu AuraGain was equally good as ETT and can be used as an alternative to tracheal intubation.[25]

The Ambu AuraGain LMA, a second generation SAD, is anatomically curved to follow the human airway and provide high seal pressures. It has gastric access, bite block and wider airway tube which provides an intubation conduit. It also has a thin and soft cuff which provides a good seal and helps in preventing gastric aspiration.[9]

Reesha Joshi et al also conducted a study in 94 children comparing Ambu AuraGain and LMA Proseal and observed that the ease and success rate for device placement, fibreoptic visualisation of larynx and the complications were comparable. However the time of insertion was shorter and mean oropharyngeal seal pressure was higher in Ambu AuraGain than in LMA Proseal group. Thus they concluded that Ambu AuraGain could become a useful alternative to LMA Proseal for securing airway in children.[9] Kriti Singh et al compared Ambu AuraGain and Proseal LMA in 60 patients undergoing laproscopic cholecystectomy. They studied OLP, number of insertion attempts, ease of insertion, time required for placement and pharyngeal muscosal pressures in both the groups. They found no difference between the two in OLP, ease of insertion and success rate of insertion at first attempt. The time taken for insertion of Ambu AuraGain was more than that of Proseal LMA with low pharyngeal mucosal pressures. Thus they concluded that Ambu AuraGain provides optimal sealing pressures and ventilation with lower pharyngeal mucosal pressures.[26]

N Jagannathan et al conducted a study in 100 children to compare the performance of Ambu AuraGain and LMA Supreme for the maintenance of airway. Ambu AuraGain demonstrated better clinical performance in

children as lesser airway manoeuvres were required to maintain a patent airway as compared to LMA Supreme.[10]

Meenakshi Sumadevi Pradeep et al conducted a study in 90 patients undergoing laproscopic surgeries comparing Ambu AuraGain, I-gel and Supreme LMA. They observed that time taken for insertion of the device was significantly higher in Ambu AuraGain but the ease of its insertion was maximum. It had comparable hemodynamics and post-operative outcome with better oropharyngeal seal and higher leak pressures and thus can be a preferred SAD over the other two devices.[27]

Ha-Jung Kim et al conducted a comparative study between Ambu AuraGain and I-gel on 68 pediatric patients from 6 months to 6 years of age undergoing surgeries of extremity. They observed that oropharyngeal leak pressure was higher with I-gel whereas fibreoptic view was better and lesser airway manoeuvres were required for placement and maintenance of airway with Ambu AuraGain. They thus concluded that Ambu AuraGain is a better option but I-gel is preferred if higher OLP is required.[28]

Lukas Gasteiger et al conducted a study in 57 patients comparing the Ambu Aura-I and Ambu AuraGain laryngeal mask. They concluded that Ambu AuraGain served as a reliable device for FOB-guided tracheal intubation as first attempt device insertion was successful in all the patients with AuraGain as compared to 97% with Aura-I.[29]

G.Preece et al conducted a study in 116 patients and compared fibreoptic guided endotracheal intubation through Ambu AuraGain and LMA Fastrack. The Ambu AuraGain allowed significantly quicker and easier endotracheal intubation. It provided better laryngeal alignment in patients with no known pathology of the airway thus making it a better conduit for tracheal intubation.[11]

OLP is a marker of safety and also helps to quantify the efficacy of seal of the laryngeal mask airway. Adequate OLP allows for positive pressure ventilation and also provides protection against gastric aspiration. C Keller et al conducted a study in 80 patients comparing various methods

to access airway sealing pressure of laryngeal mask airway. Test 1 is Audible noise: detection of audible noise by listening over the mouth. Test 2 is Oral capnography: place a 5cm carbon dioxide sampling line inside the mouth alongside the LMA and note when the carbon dioxide was first seen above baseline on the monitor screen. Test 3 is Manometric stability: observe aneroid manometer dial as the pressure from the breathing system is increased and note the airway pressure at which the dial reached stability i.e. the airway pressure at which the leak was in equilibrium with fresh gas flow. Test 4 is Auscultation: detection of an audible noise using a stethoscope placed lateral to the thyroid cartilage. They concluded that all four airway sealing pressure tests were excellent for clinical purposes but manometric stability test provided higher mean value and inter-observer reliability making it better for researchers.[30]

Optimal size selection is critical to the safe and effective use of the laryngeal mask airway. Ideally the optimal size LMA should be easy to insert, have an oropharyngeal leak pressure sufficient for positive pressure ventilation, a pharyngeal mucosal pressure less than capillary perfusion pressure and be positioned such that instruments pass easily into the respiratory tract.[31] In order to select LMA of appropriate size for its safe and effective use, various studies have been conducted. These studies concluded that selection of size of LMA is based upon various factors namely body weight, sex of the patient, upper airway geometry and anatomical features.

A.S. Rao et al conducted a study in 2003 to determine optimal size of LMA in 135 Malaysian female adults. They compared LMAs of size 3, 4 and 5. Optimisation of size of LMA was based on 4 parameters: oropharyngeal leak pressure, fibreoptic score, number of attempts at placement and percentage of vocal cord seen. They concluded that LMA of size 4 was optimal for use in Malaysian adult females.[32]

Asai et al conducted a study in 1998 to compare size 3 and size 4 laryngeal mask in females and size 4 and size 5 in males for success

rate of insertion, incidence of airleak and pressure exerted on pharynx. They found that sizes 4 and 5 were superior to sizes 3 and 4 for females and males respectively and did not produce higher pressures on the pharyngeal mucosa.[33]

Berry et al conducted a study in 2002 in 30 apnoeic anaesthetised adults weighing <100kg and size 3, 4, 5 were inserted in each patient in random order and they found that size 5 LMA was optimal in 63% of adult patients, size 4 in 37% and size 3 was never optimal.[34]

In clinical practice, the most commonly used method for size determination is weight based method. However it is not suitable in many patients due to wide range for each category of weight, variation in size and individual anatomy and for overweight or underweight as it is based on actual body weight rather than ideal body weight. H. J. Kim et al compared conventional laryngeal mask airway sizing according to actual weight and ideal weight in over- and underweight children and concluded that in overweight children LMA size based on patients' weight is appropriate while in underweight children, LMA size by an ideal weight is better.[35]

Syafri Kamsul Arif et al also compared actual and ideal body weight for size selection of I-Gel LMA in 22 obese patients. A significant higher first attempt insertion rate, shorter insertion time and easier placement was observed in ideal body weight group and they concluded that ideal body weight is better for size selection of the I-Gel LMA in obese patients than the actual body weight.[36]

No similar method exists for rough estimation of the required LMA size. Thus various studies are being conducted to find an effective alternative method to the existing weight based method of size determination of LMA.

Meilin Weng et al conducted a study to compare the efficacy of LMA supreme placement when the size was determined by thyromental distance as compared to body weight. So 80 patients were enrolled in the study and randomly allocated into 2 groups. In thyromental distance

based group, most used LMA was size 4 followed by size 3. Whereas in weight based group, most commonly used was size 4 followed by size 5. They concluded that thyromental distance based method is better as compared to weight based method in terms of guaranteeing better ventilation, easier device placement and a reliable pharyngeal seal.[14]

A study was conducted by Xia Wang et al on 70 female patients undergoing breast cancer surgery. They determined the size of LMA by weight based method in one group and ultrasound guided hyomental distance based method in the other group. The selection of correct size of LMA without any need of size adjustment, injury rate, OLP and insertion attempts were recorded. They concluded that the hyomental distance based method was better than the weight based method for determining the size of LMA-classic in terms of low chances of injury, lesser number of insertion attempts with similar excellent OLP value.[37]

Yi-Hsuan Huang et al conducted a study on 21 male patients for selection of optimal size of LMA based on tongue width method. The LMA would be selected with the widest width of each LMA corresponding to the same width as that of the tongue of the patient. Frequency of insertion attempts, presence of cuff in the mouth, end tidal CO_2 shown on monitor, oropharyngeal leak pressure and fibreoptic score were measured following each LMA insertion. The authors concluded that tongue width based method is a convenient and efficacious alternative to weight based method for selecting optimal size LMA.[15]

Gallart et al compared the traditional weight based method for estimation of size of LMA with a method using combined width of patient's index, middle and ring fingers. They found agreement between both the methods with disagreement of only one size in 22% of cases.[13]

Zahoor et al in 2012 studied 210 pediatric patients aged 6 months to 15 years to determine if the size of external ear, which also resembles the shape of the LMA, could act as a proxy for finding the adequate size of LMA. They found the success rate to be 93.3% in terms of insertion in first attempt and being able to achieve adequate ventilation. The author

thus concluded that auricular size could be used as an additive method to the existing standard methods.[16]

Murat Haliloglu et al conducted a study in 2017 for determining the size of ProSeal LMA in 197 children. The correct size was determined according to the size of the auricle in children and the results were compared with the standard weight based method. Insertion and adequate ventilation was recorded in 185 patients in the first attempt and 12 required a second attempt and they concluded that the auricle based method for determining the size of ProSeal LMA is useful compared with the manufacturer's weight based formula.[5]

Uma Kamath et al in 2019 compared pinna size based method to weight based method in 100 pediatric patients under the age of 15 years. Parameters such as number of attempts and change of the size of LMA were monitored. They concluded that pinna size based estimation for determining the size of LMA is a convenient and feasible alternative to traditional weight based estimation.[38]

A study was conducted by Ramya Ravi et al in 204 pediatric patients comparing pinna size based and weight based method for determining the size of Proseal LMA(PLMA). They studied oropharyngeal sealing pressure, number of attempts for successful placement of PLMA, peak airway pressure, gastric tube placement, traumatic insertion and post-operative complications. They concluded that pinna based method can be used as an alternative to size selection of PLMA in pediatric population for positive pressure ventilation as no significance difference was seen in both the groups with respect to the outcomes measured.[39]

MATERIALS AND METHODS

SOURCE OF DATA:

The study was conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval from the hospital ethics committee. A written informed consent was obtained from all patients selected for study.

METHOD OF COLLECTION OF DATA:

A prospective, randomised, interventional study was conducted on ASA I, II and III adults. A total of 120 patients were recruited in the study and an equal number were randomised using computer generated random numbers contained in sealed, sequentially numbered envelopes, which were opened by an independent anaesthesiologist.

Inclusion criteria: Healthy individuals of age more than 18 years with American Society of Anaesthesiologists' (ASA) physical status I, II and III, scheduled for elective surgery in supine position.

Exclusion criteria:

- Age <18 years
- BMI >35kg/m^2
- High risk of regurgitation or aspiration
- Limited mouth opening
- Infections or pathological abnormality of oral cavity or pharynx
- Patients with h/o hiatus hernia or gastroperesis
- Pregnancy
- Structural ear deformity

Group Allocation - A written informed consent was obtained from all the patients. Patients were divided into 2 groups of 60 patients each.

Group (A): AuraGain LMA size was selected based upon the size of the auricle of the patient.

Group (B): AuraGain LMA size was selected based upon weight of the patient.

Anaesthesia technique - All patients were subjected to routine pre-operative assessment and standard fasting protocols.

An appropriate size AuraGain LMA was selected using the technique randomly allocated to that particular patient. AuraGain LMA size in group (A) was selected by measuring the size of the auricle with a ruler in the vertical and horizontal dimensions in cms. Vertical ear length was measured from the most dependent portion of the lobule to the furthest portion of the auricle. Horizontal ear length was measured from the tragus to the furthest part of the helix horizontally.

Table 1: Size of LMA according to auricle size

	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5
Vertical(cm)	6.5	8	9	10
Horizontal(cm)	4	5.5	5.75	6.25

The size of LMA to be used was based on the above dimensions. The nearest corresponding size of partially inflated LMA was chosen and inserted after induction. If the auricle size fell between two sizes of Aura LMA, the larger size was considered. LMA one size larger and one size smaller was available for exchange if the approximation was incorrect. The size of LMA in group (B) was based on patient's weight as per the manufacturer's guidelines (20-30kg – size 2.5, 30-50 kg - size 3, 50-70 kg - size 4, >70 kg - size 5).[8,9]

In the operating room, all patients were positioned in supine position with 10cm pillow underneath head. Monitors were attached in the form of pulse oximeter, non invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$) and 5 lead electrocardiography (ECG). Intravenous access was secured. Premedication was given in the form of intravenous injections of midazolam 0.02 mg/kg, metoclopramide 10 mg and glycopyrrolate 0.2 mg. Fentanyl was used for intraoperative analgesia in the dose of 2mcg/kg intravenous. After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical face mask, anaesthesia was induced with 1% propofol 2-2.5 mg/kg

titrated to loss of verbal response. Neuromuscular blockade was achieved by intravenous injection of atracurium 0.5 mg/kg. After achieving adequate jaw relaxation, the head was placed in sniffing position. The selected AuraGain LMA cuff was lubricated with a water based jelly and inserted. Anaesthesiologists having a minimum of one year experience with supraglottic devices and having inserted more than 50 of them were involved in the study. An independent observer noted the time of insertion of LMA. After insertion, the cuff was inflated with air to a pressure of 60cm of H_2O using a cuff manometer. The lungs were mechanically ventilated using volume controlled ventilation set to deliver a tidal volume of 8ml/kg, respiratory rate to maintain $EtCO_2$ between 30 and 40 mmHg, inspiratory and expiratory ratio of 1:2 and a positive end-expiratory pressure of 5 cm of water. Initial assessment of ventilation was performed by observing the square wave capnograph and chest rise. Oropharyngeal leak pressure(OLP) was measured by adjusting the fresh gas flow to 3L/min and closing the adjustable pressure limiting valve of the circle system, the minimum airway pressure at which audible gas leak starts to occur as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures were not allowed to exceed 40 cm of H2O.[40] The total fresh gas flow was maintained at 3 L/min. Anaesthesia was maintained using isoflurane 1-2% in 50:50 oxygen and air. A nasogastric tube of appropriate size was passed through the gastric tube channel in all the cases. In case of failed passage of LMA into the pharynx or ineffective ventilation (expiratory TV <5mg/kg) or absence of a capnography tracing, the LMA was removed and a smaller or a larger size was attempted respectively. If successful insertion was not achieved even after second attempt, endotracheal intubation was done and this was regarded as a failure of insertion of supraglottic device. At the end of the procedure after confirming the return of spontaneous ventilation, neuromuscular blockade was reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.006 mg/kg and LMA was removed once the patient gained consciousness. Patients were shifted to post-anaesthesia care unit for observation.

PRIMARY OUTCOME:

First attempt success rate - The number of patients with successful insertion of LMA in the first attempt. It was confirmed by observing visible chest rise, bilateral chest auscultation, appearance of a square wave end-tidal carbon dioxide waveform and oral leak pressure (OLP).

SECONDARY OUTCOMES:

Number of attempts – Number of attempts needed for successful placement were recorded. A maximum of two attempts were allowed.

Insertion time of Aura LMA - The insertion time was defined as the duration from when the anaesthesiologist picks up the LMA till the capnography tracing is obtained.

Difficulty of insertion – The anaesthesiologist inserting the device was to provide a subjective assessment of the insertion procedure by grading it as easy=1, moderate=2, difficult=3 and impossible=4.

Insertion failure – If we were unable to place the LMA successfully even after 2 attempts, it was considered as failure to insert.

Respiratory Parameters – Expired Tidal Volume, Peak Pressure, Plateau Pressure and $EtCO_2$ were recorded.

Adverse events – At the time of removal of Auragain LMA, any staining of the LMA with blood was noted.

Number of episodes of desaturation i.e., SpO_2 < 90% were noted down, the patients were mask ventilated with 100% oxygen till optimal SpO_2 level was reached (95%).

Dental injury if any was noted down.

Patients were followed up for 12 hours after the surgery for complaints of sore throat, dysphagia and dysphonia.

Sore throat was rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up in post anaesthesia care unit. A score of more than 4 on NRS was considered as sore throat.[41]

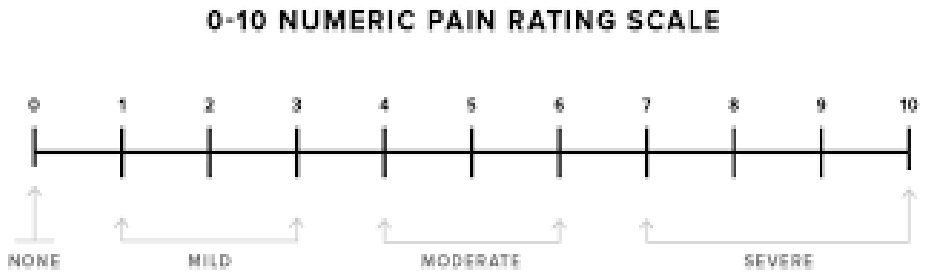

Figure 1: Numeric Pain Rating Scale

Statistical Analysis:

Data was described in terms of range; median (inter quartile range IQR), mean ± standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups was done using ANOVA. For comparing categorical data, Chi square ($\chi 2$) test was performed and Fischer exact test was used when the expected frequency was less than 5.A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations was done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

Sample size calculation:

The alpha level used for this analysis was $p<0.05$ and beta was 0.20. Sample size was estimated from the results of previous study using requirement of changing LMA as the parameter, which is the primary outcome of our study.[38] Our sample size came out to be 60 subjects per group at power of 0.99 and with an effect size of 1 with 10% chance of error with $\alpha = 0.05$, $\beta = 0.20$ and confidence interval of 95%.

OBSERVATIONS AND RESULTS

CONSORT Flow Diagram of the study

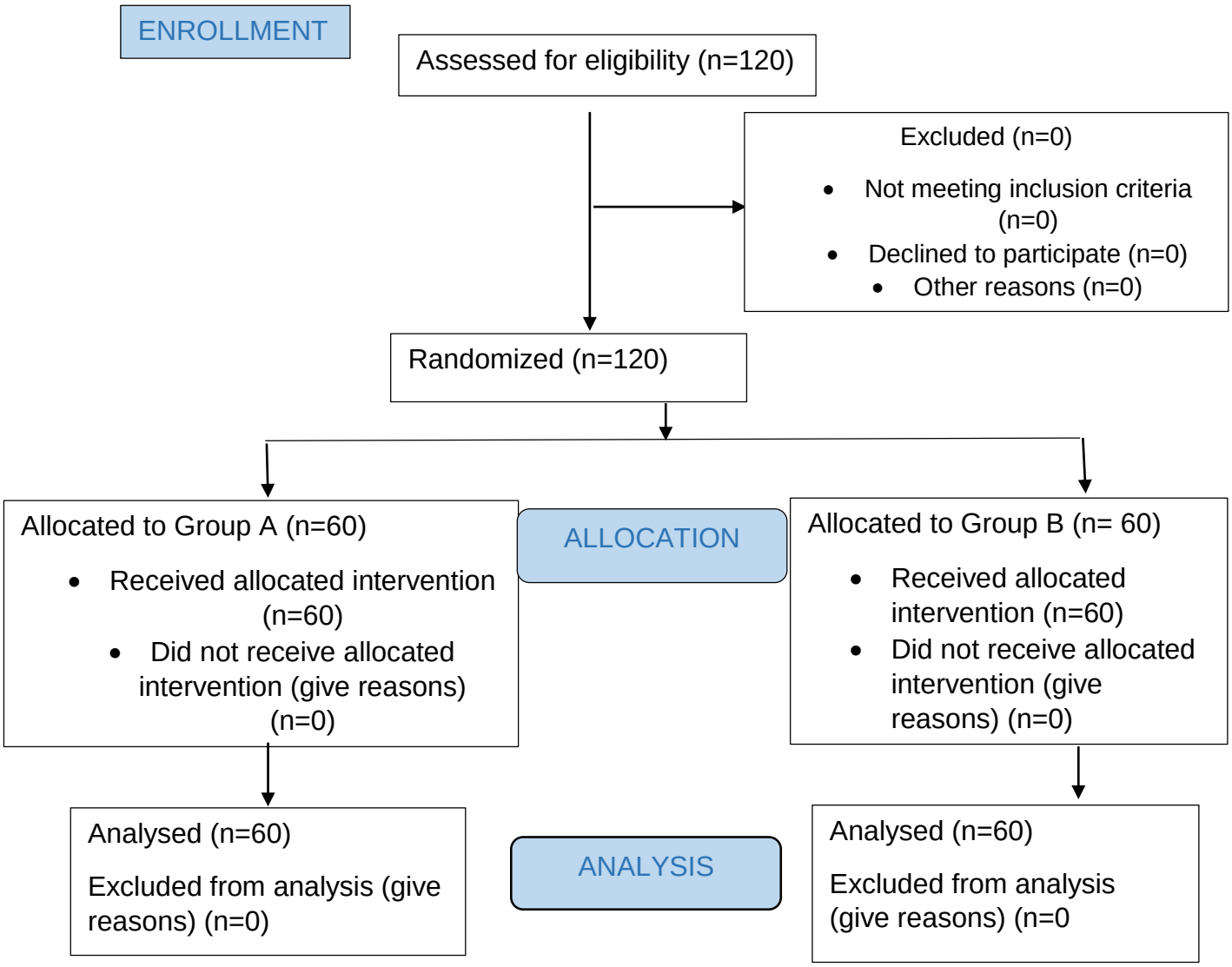

Figure 2: Consort flow diagram of the study

A total of 120 patients were studied. They were divided into 2 groups of 60 patients each and were randomly allocated to either of the groups by computer generated random numbers.

Table 2: Distribution of patients according to age (years)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Age	39.10	12.27	38.55	11.61	-0.084	0.933

Both the groups were comparable with respect to age. Mean age in Group A was 39.10± 12.27 years and that of Group B 38.55 ±11.61 years.

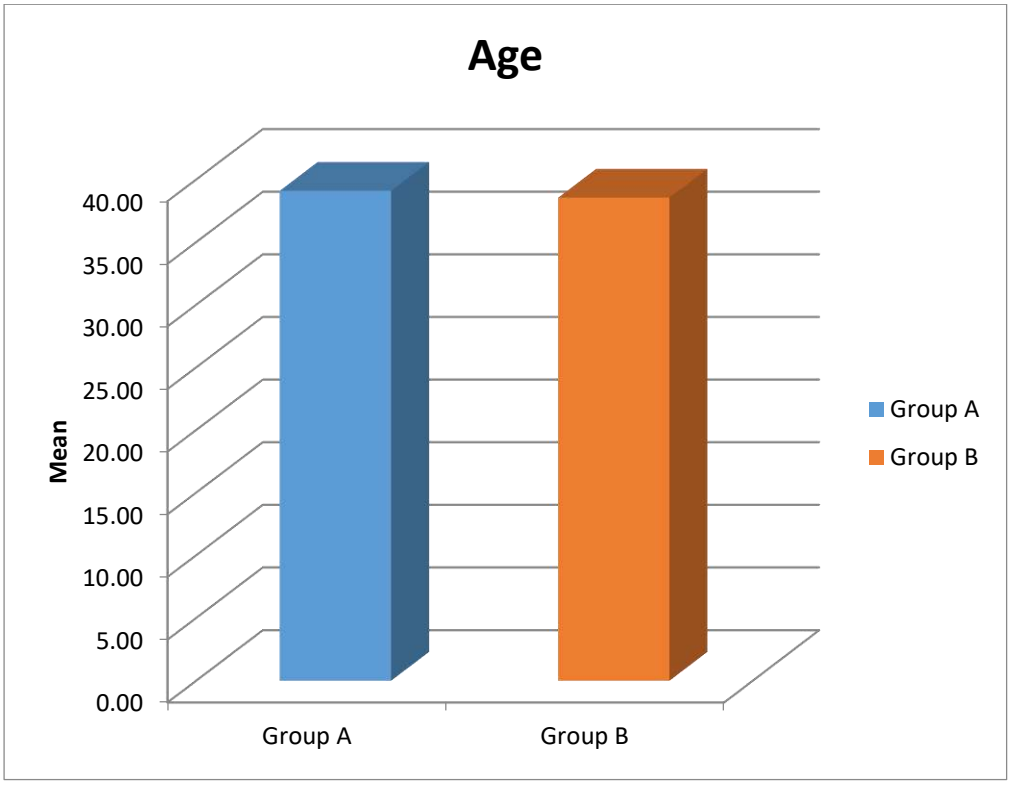

Figure 3: Distribution of patients according to age (years)

Table 3: Distribution of patients according to gender

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Sex	F	44	73.3%	45	75.0%	89	0.043	0.835
	M	16	26.7%	15	25.0%	31		
Total		60	100.0%	60	100.0%	120		

The two groups were comparable with respect to gender with more of female patients as compared to male patients. In Group A, there were 73% females and 27% males and in Group B there were 75% females and 25% males.

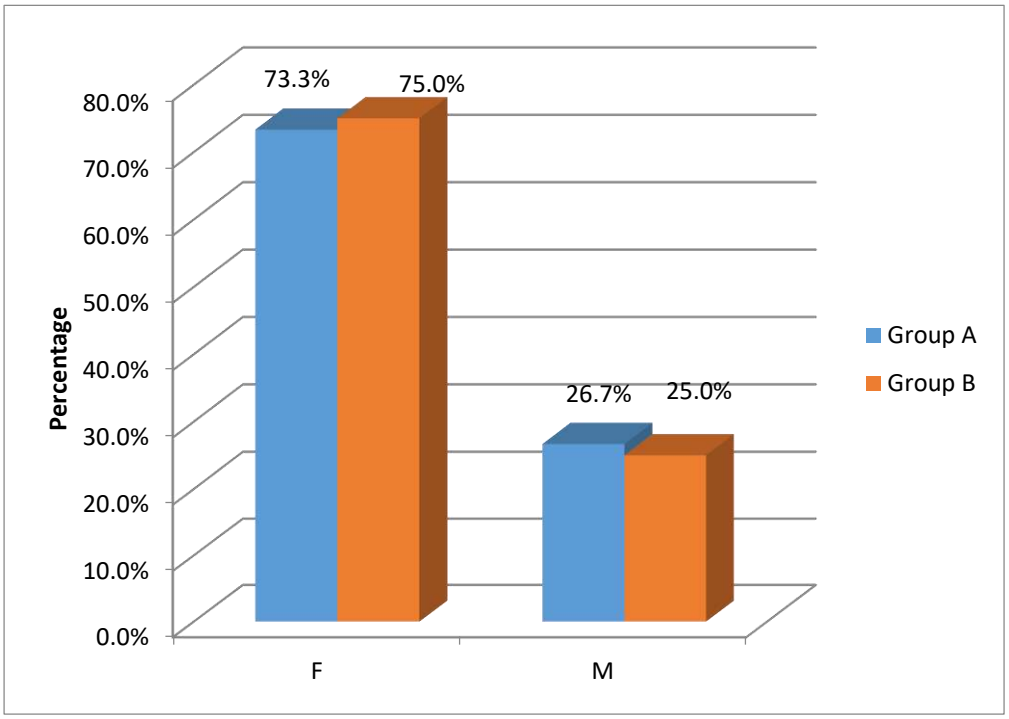

Figure 4: Distribution of patients according to gender

Table 4: Distribution of patients according to height (cm), weight (kg) and BMI

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Height(cm)	160.78	5.78	161.90	7.12	-0.642	0.521
Weight(kg)	65.62	11.37	66.93	14.11	-0.231	0.817
BMI	25.40	4.31	25.35	4.10	-0.024	0.981

Both the groups were comparable with respect to height (cm), weight (kg) and BMI (kg/m²). The mean height of Group A was 160.78±5.78cm and of Group B was 161.90±7.12cm.

Similarly, mean weight of Group A 65.62 ± 11.37kg and Group B was 66.93±14.11 kg.

Mean BMI of Group A was 25.40 ± 4.31kg/m² and in Group B was 25.35 ± 4.10 kg/m²

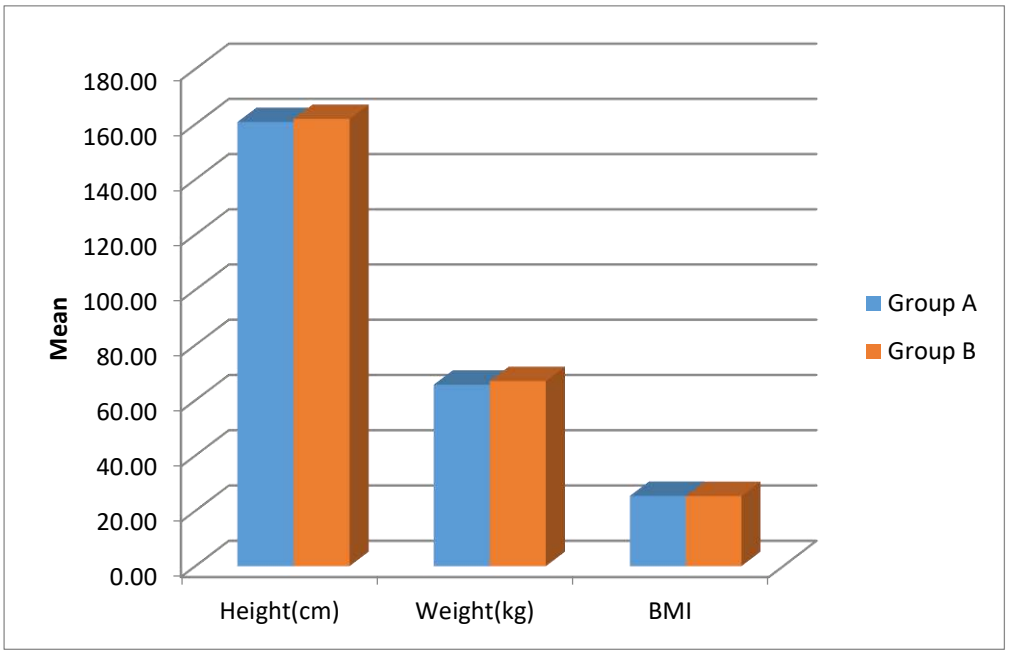

Figure 5: Distribution of patients according to height (cm), weight (kg) and BMI

Table 5: Distribution of patients according to ASA grading

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
ASA Grade	I	36	60.0%	43	71.7%	79	2.435	0.296
	II	17	28.3%	10	16.7%	27		
	III	7	11.7%	7	11.7%	14		
Total		60	100.0%	60	100.0%	120		

The two groups were comparable in terms of ASA grading. 60% of patients of group A and 71.7% of group B belong to ASA I. Both the groups had similar number of patients (11.7%) belonging to ASA Grade III.

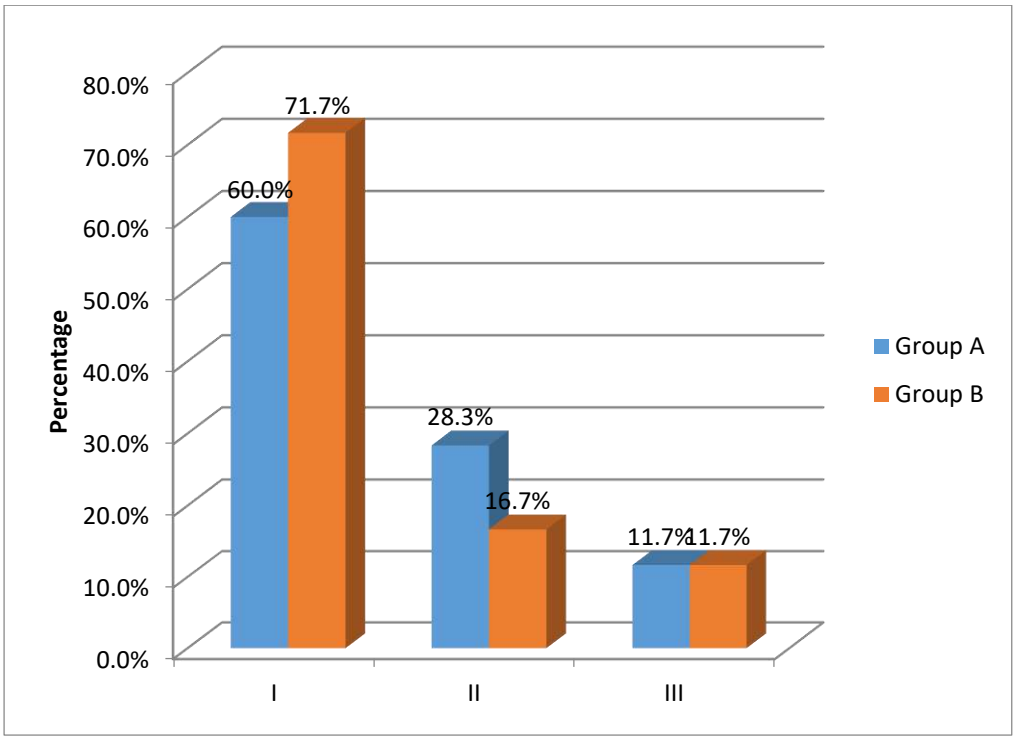

Figure 6: Distribution of patients according to ASA grading

Table 6: Distribution according to mean duration of surgery

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Duration of surgery(min)	57.25	32.77	61.00	31.65	-0.985	0.324

The two groups were comparable in terms of duration of surgery with mean duration of surgery for group A being 57.25±32.77 min and Group B being 61.00 ±31.65 min.

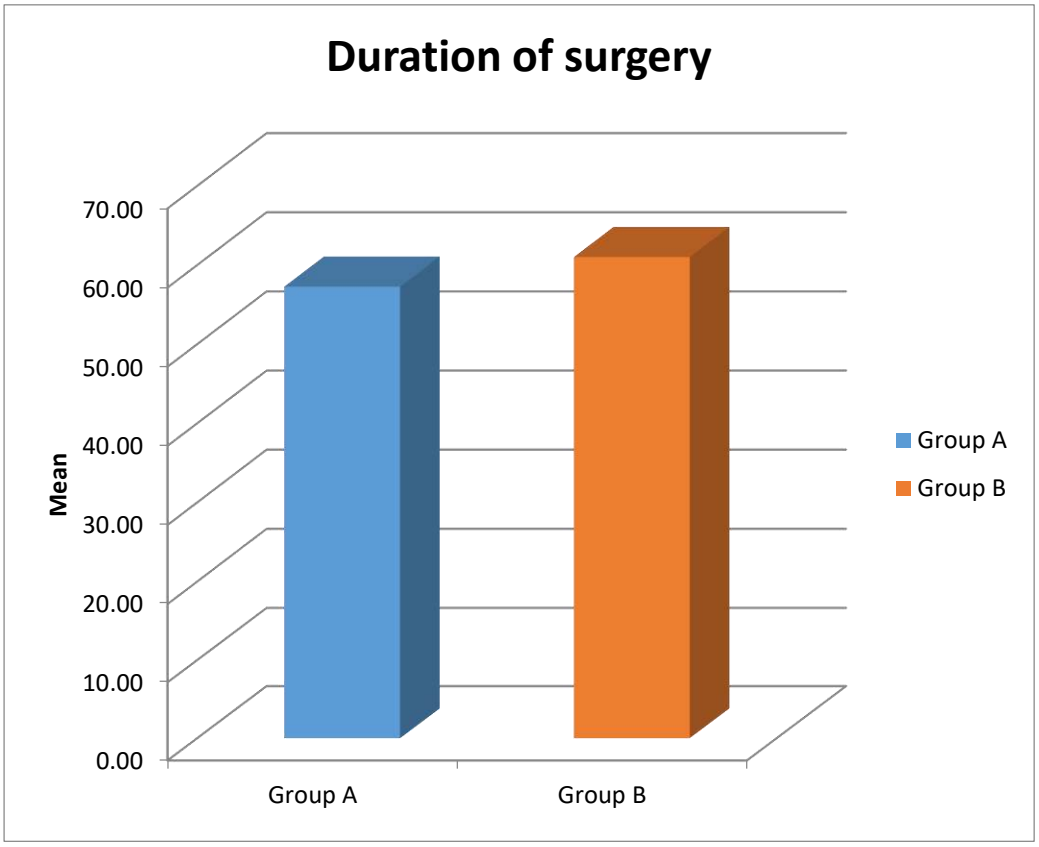

Figure 7: Distribution according to mean duration of surgery

Table 7: Distribution according to size of Ambu AuraGain inserted

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Size of AuraGain LMA inserted	2.5	12	20.0%	0	0.0%	12	92.571	0.001
	3	48	80.0%	8	13.3%	56		
	4	0	0.0%	35	58.3%	35		
	5	0	0.0%	17	28.3%	17		
Total		60	100.0%	60	100.0%	120		

The size of Ambu AuraGain LMA used in Group A were 2.5 and 3 in 20% and 80% patients respectively and the sizes used in Group B were 3, 4 and 5 (13.3 %, 58.3%,28.3% respectively). Most commonly used size of Ambu AuraGain LMA in group A was size 3 and in group B was size 4.This was found to be statistically significant.

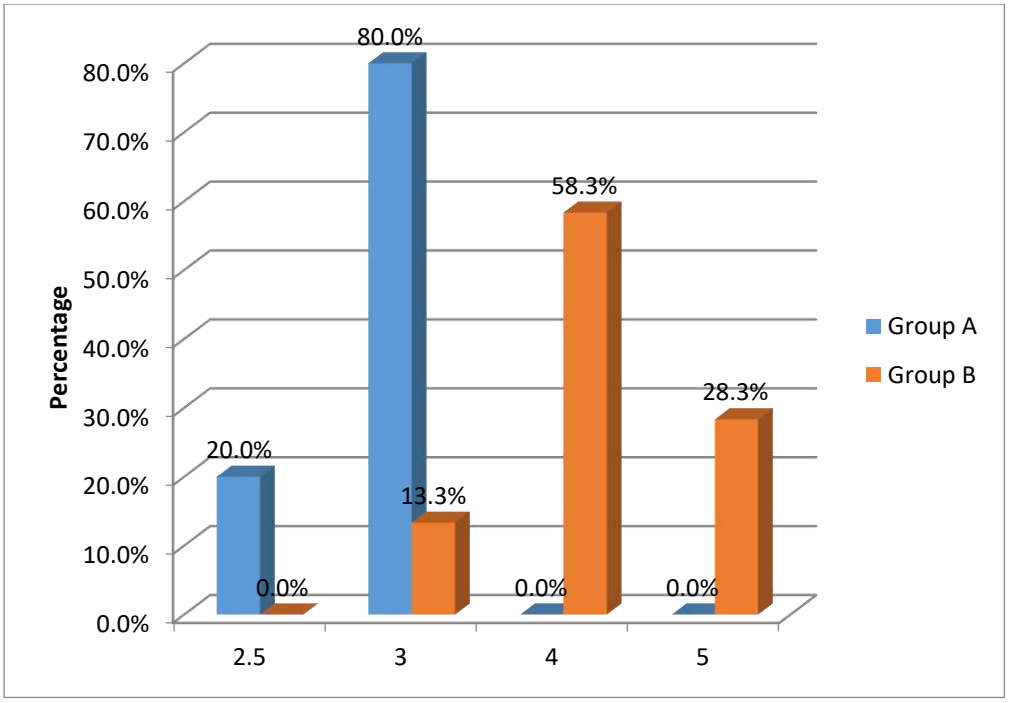

Figure 8: Distribution according to size of Ambu AuraGain inserted

Table 8: Distribution according to mean insertion time

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Insertion time(sec)	14.05	1.97	16.12	2.50	-5.355	0.001

The mean time of insertion of Group A was 14.05 ± 1.97 seconds and that of Group B was 16.12 ± 2.50 seconds. The difference in mean time of successful insertion of Ambu AurGain among the groups was found to be statistically significant (p-value 0.001).

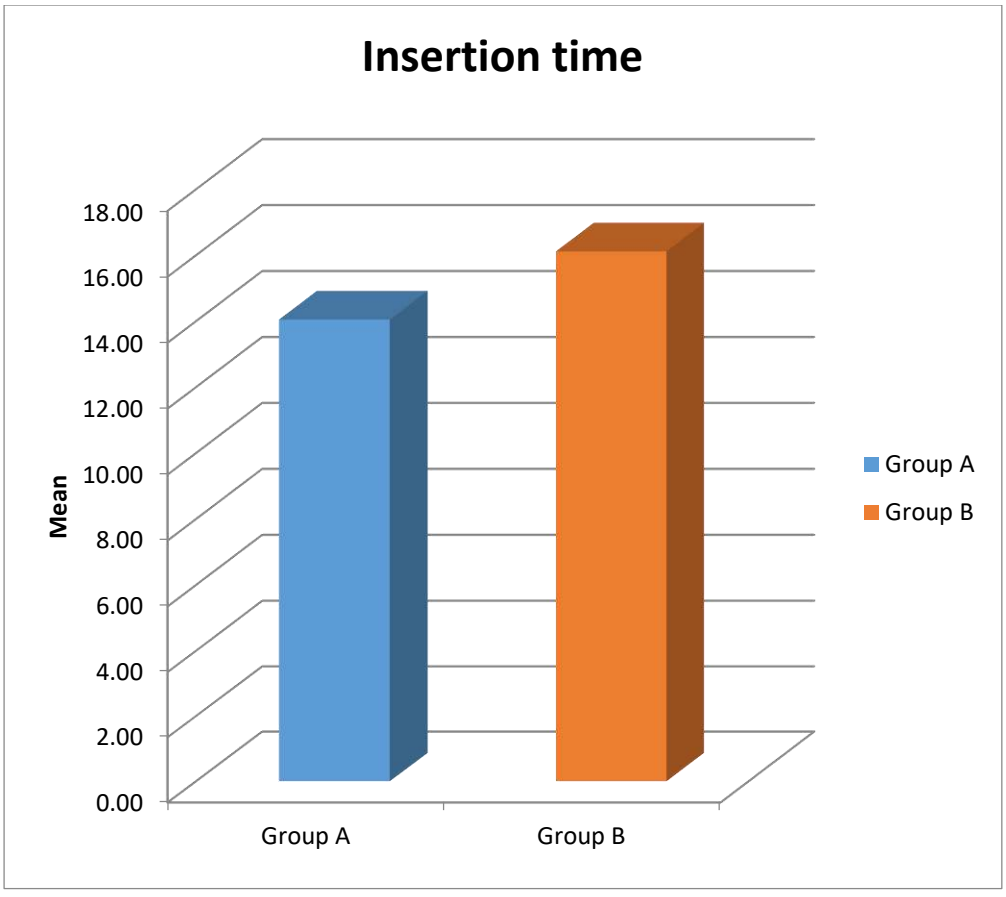

Figure 9: Distribution according to mean insertion time

Table 9: Distribution according to parameters of successful insertion of Ambu AuraGain

		Group A		Group B		Total	Chi-square value	p-value
Visible chest rise	N	3	5.0%	8	13.3%	11	2.502	0.114
	Y	57	95.0%	52	86.7%	109		
Bilaterally equal chest auscultation	N	3	5.0%	8	13.3%	11	2.502	0.114
	Y	57	95.0%	52	86.7%	109		
Appearance of a square waveform EtCO2	N	3	5.0%	8	13.3%	11	2.502	0.114
	Y	57	95.0%	52	86.7%	109		
Total		60	100.0%	60	100.0%	120		

The parameters of successful insertion of Ambu AuraGain LMA studied are visible chest rise, bilaterally equal chest auscultation and appearance of a square waveform ETCO2.

In group A, successful insertion of LMA was not seen in 3 patients (5%) and in group B in 8 (13.3%) patients in the first attempt.

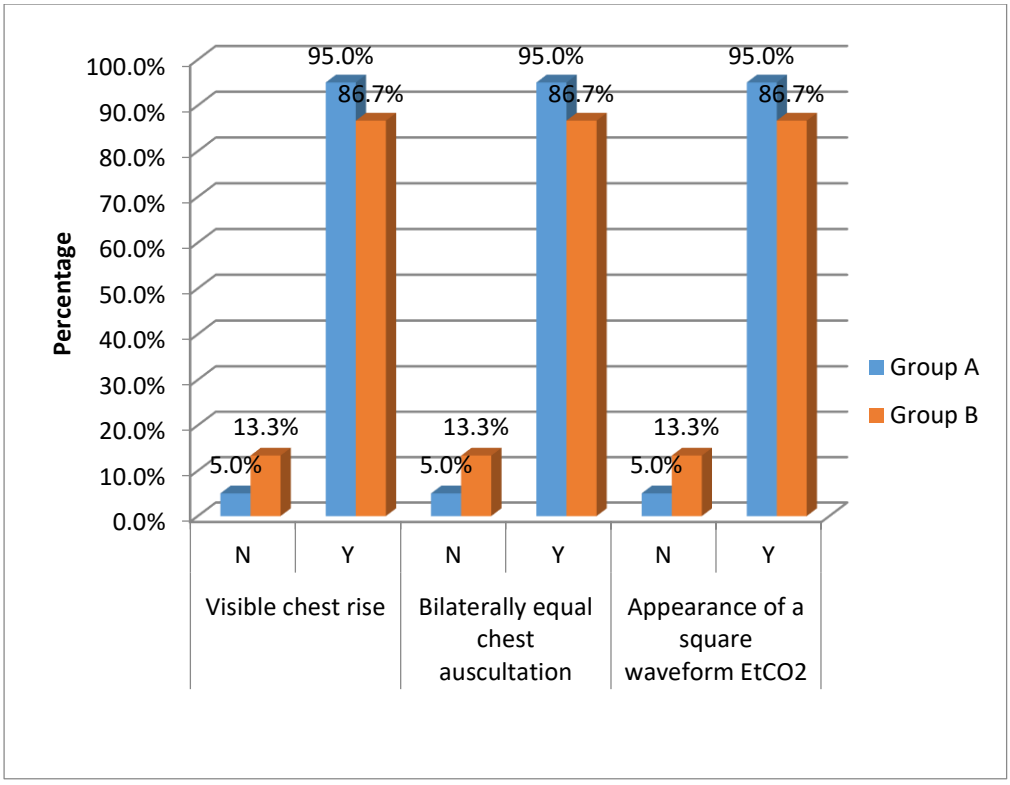

Figure 10: Distribution according to parameters of successful insertion of Ambu AuraGain

Table 10: Distribution according to mean OLP

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Oral leak pressure >10cm H_2O	24.60	2.53	30.53	1.80	-8.889	0.001

There was a statistically significant difference in the OLP of both the groups with a p-value of 0.001. The mean OLP of Group A was 24.60±2.53 cm H_2O and that of Group B was 30.53 ± 1.80 cm H_2O.

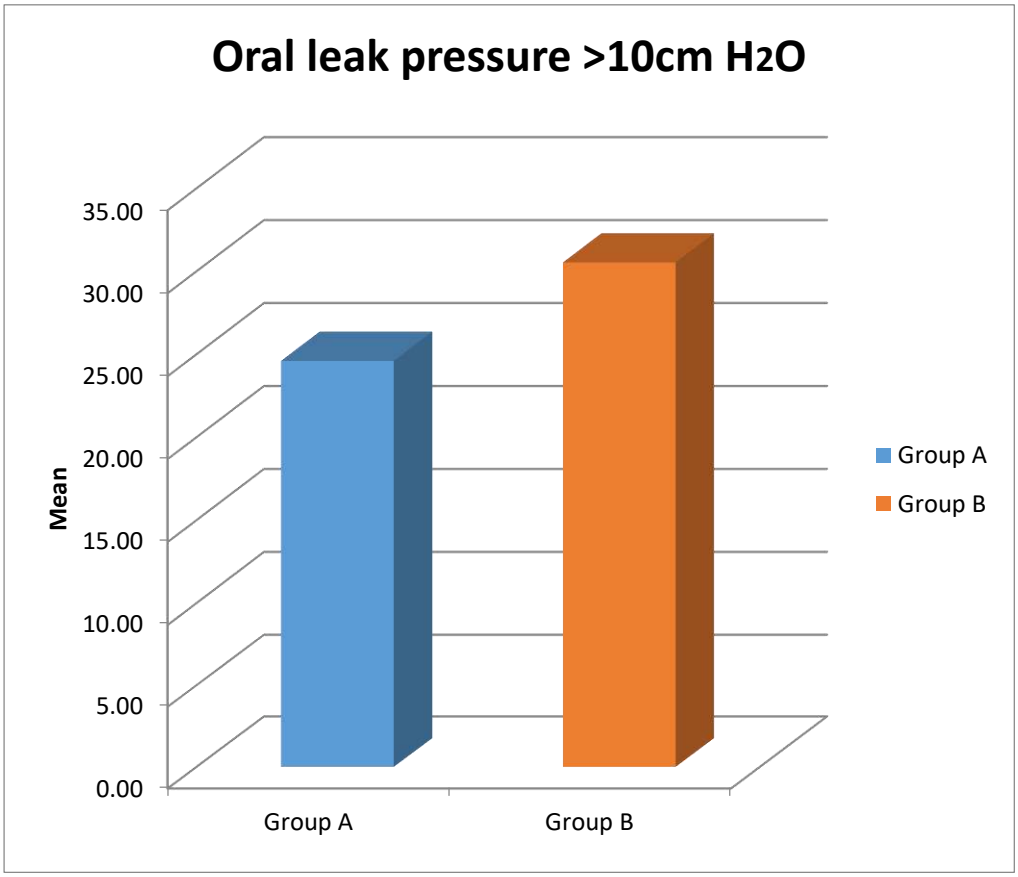

Figure 11: Distribution according to mean OLP

Table 11: Distribution according to number of insertion attempts

		Group A		**Group B**		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Insertion attempts	1	57	95.0%	52	86.7%	109	2.502	0.114
	2	3	5.0%	8	13.3%	11		
Total		60	100.0%	60	100.0%	120		

95% patients in group A and 86.7% in group B had successful placement of Ambu AuraGain in 1st attempt. Second attempt was required in 3 patients (5%) in group A and 8 patients(13.3%) in group B.

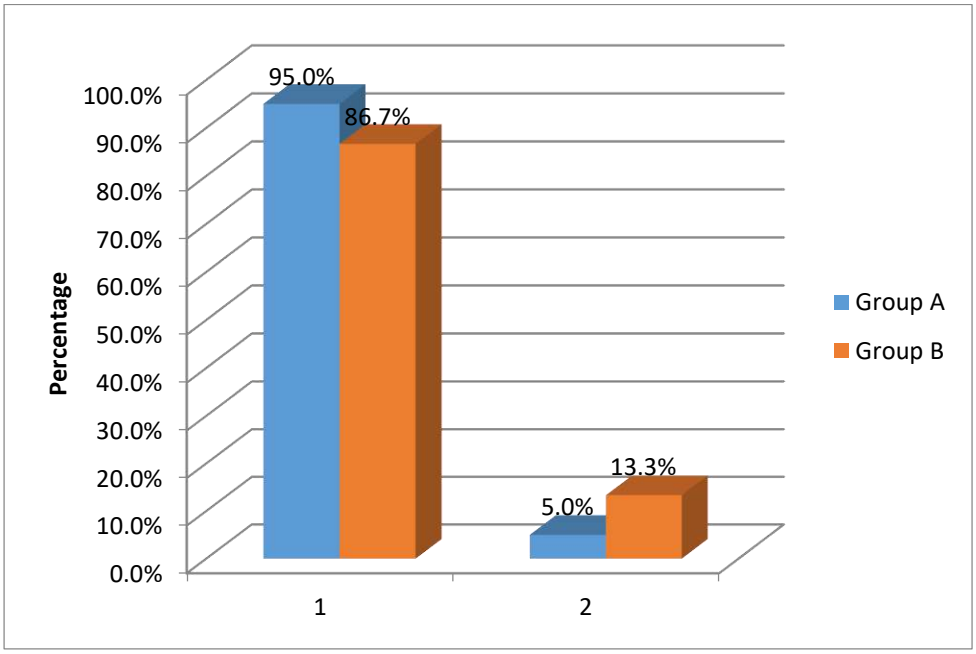

Figure 12: Distribution according to number of insertion attempts

Table 12: Distribution according to change in size of Ambu AuraGain required

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Any change in the size of device required	N	57	95.0%	52	86.7%	109	2.502	0.114
	Y/4	3	5.0%	8	13.3%	11		
Total		60	100.0%	60	100.0%	120		

The change in device required in group A was in 3(5%) patients and in group B was in 8(13.3%) patients.

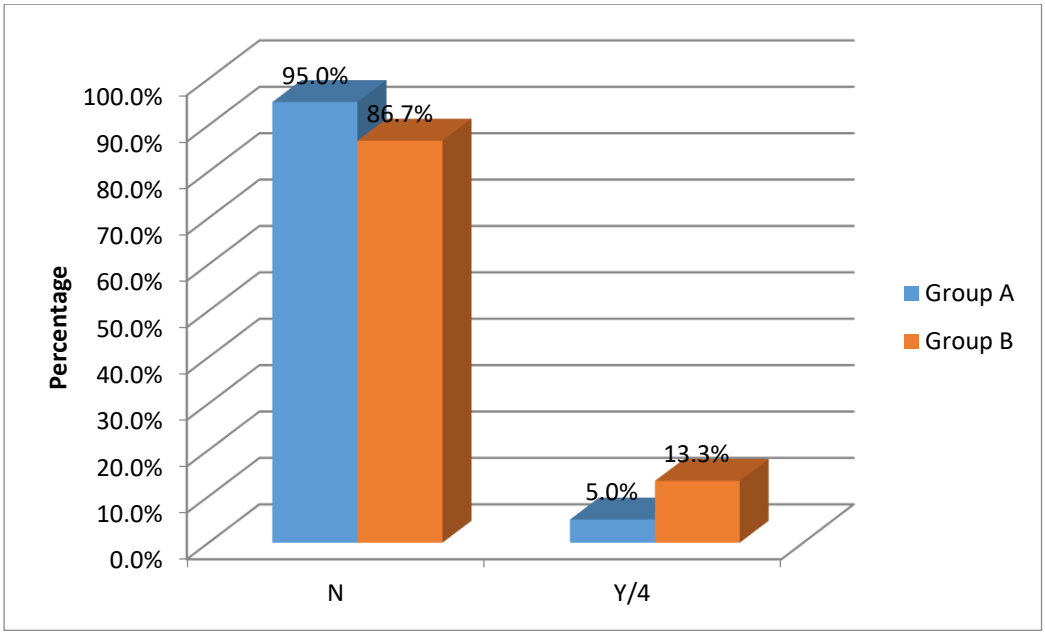

Figure 13: Distribution according to change in size of Ambu AuraGain required

Table 13: Distribution of insertion attempts in two groups according to gender

GROUP			Sex		Total
			F	M	
Group A	Insertion attempts	1	44	13	57
		2	0	3	3
	Total		44	16	60
Group B	Insertion attempts	1	38	14	52
		2	7	1	8
	Total		45	15	60

The change in device was not required in female patients but 3 male patients in group A whereas change in LMA size was done in 7 female patients and 1 male patient in group B.

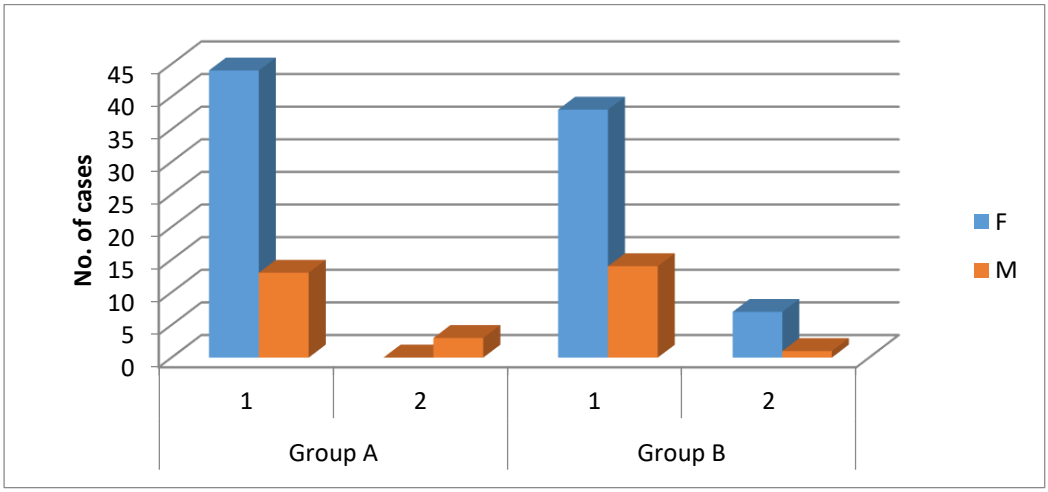

Figure 14: Distribution of insertion attempts in two groups according to gender

Table 14: Distribution according to difficulty of insertion of Ambu AuraGain

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Difficulty of insertion	EASY	44	73.3%	0	0.0%	44	71.754	0.001
	MODERATE	16	26.7%	49	81.7%	65		
	DIFFICULT	0	0.0%	11	18.3%	11		
Total		60	100.0%	60	100.0%	120		

The difficulty of insertion as graded by the anaesthesiologist inserting the device for Group A was easy in 73% and moderate in 27% of the patients while in Group B it was moderate in 82% of the patients and difficult in 18%. The results of the two groups were statistically significant.

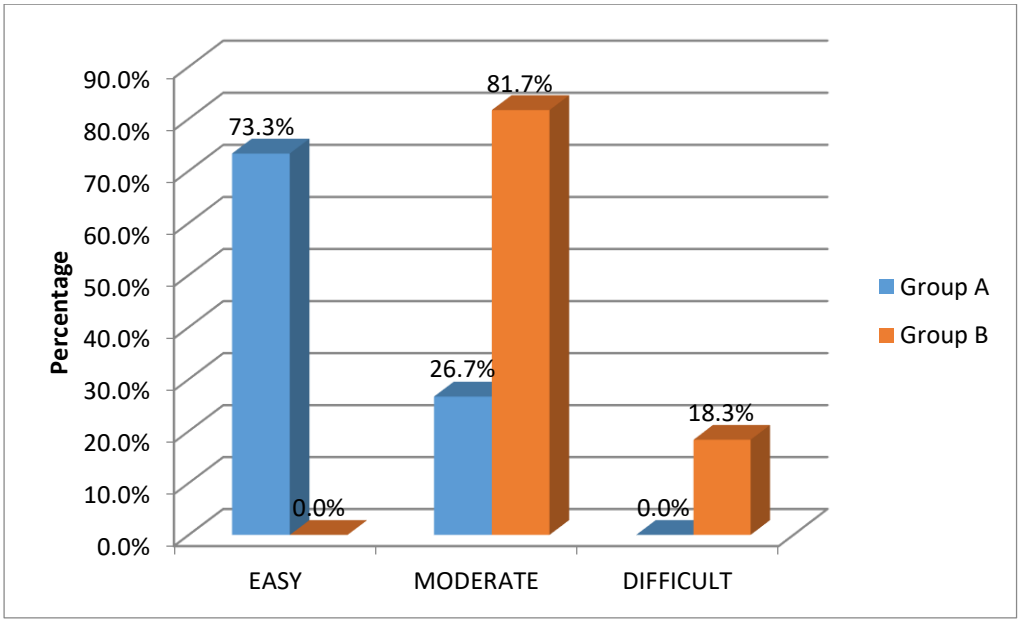

Figure 15: Distribution according to difficulty of insertion of Ambu AuraGain

Table 15: Distribution according to post-operative complications

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Desaturation episodes	N	60	100.0%	60	100.0%	120		
Dental injury	N	60	100.0%	57	95.0%	117	3.077	0.079
	Y	0	0.0%	3	5.0%	3		
Blood staining	N	59	98%	30	50.0%	89	36.578	0.001
	Y	1	2%	30	50.0%	31		
Dysphagia	N	60	100.0%	60	100.0%	120		
Dysphonia	N	60	100.0%	41	68%	101	22.574	0.001
	Y	0	0.0%	19	32%	19		

There were no desaturation episodes in any of the 2 groups.

Dental injury was not seen in group A but was seen in 5% of patients in group B.

Blood stained LMA was seen in 2% in group A and 50% in group B.

There was no dysphagia in any of the 2 groups.

Dysphonia was not seen in group A but was present in 32% in group B.

The presence of blood staining and dysphonia were statistically significant.

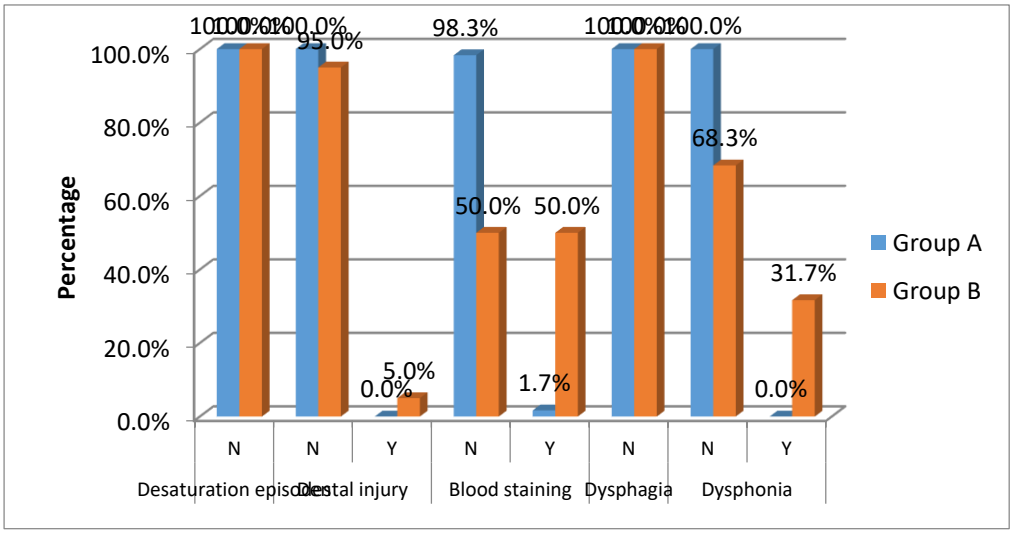

Figure 16: Distribution according to post-operative complications

Table 16: Distribution according to sore throat rating scale

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Sore throat rating scale	1	12	20.0%	0	0.0%	12	80.007	0.001
	2	34	56.7%	3	5.0%	37		
	3	14	23.3%	15	25.0%	29		
	4	0	0.0%	21	35.0%	21		
	5	0	0.0%	21	35.0%	21		
Total		60	100.0%	60	100.0%	120		

The presence of sore throat was found to be statistically significant in the 2 groups.

Sore throat was observed in all patients although the grade of sore throat was significantly milder in group A(1-3) as compared to group B (1-5)

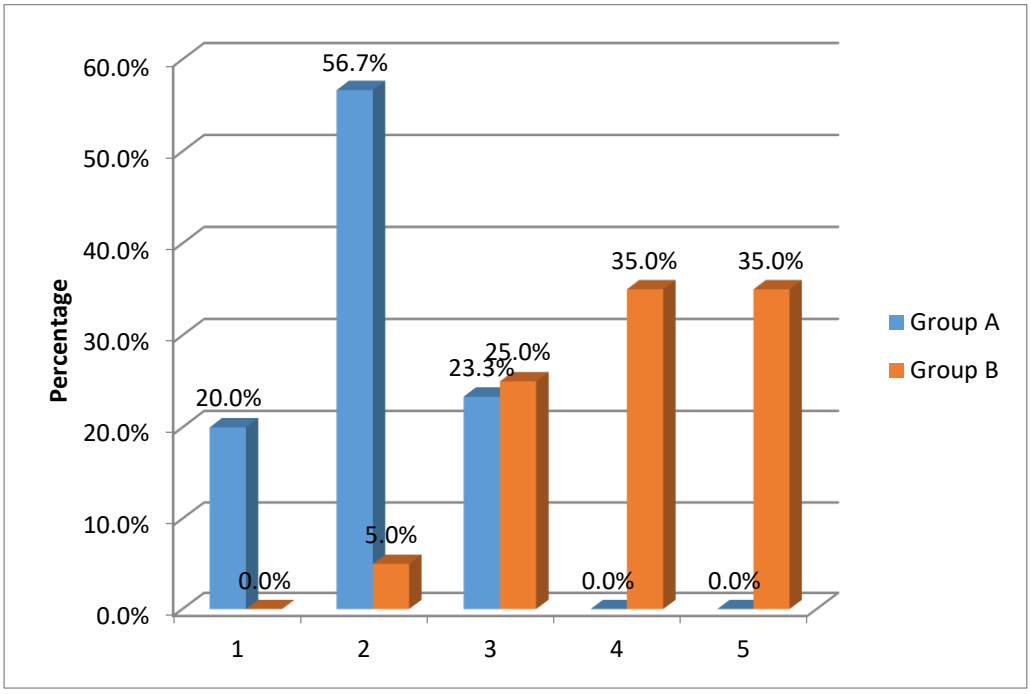

Figure 17: Distribution according to sore throat rating scale

DISCUSSION

The Laryngeal Mask Airway is a supraglottic airway device which sits outside the larynx and creates a seal around it to maintain the patency of the airway. It is being widely used in the operating room as well as in the emergency care settings. It is non-invasive as compared to endotracheal tube and has now emerged as a better choice in cases where endotracheal intubation is not mandatory. LMA also allows for a hands free approach to the airway management as compared to the facemask. The use of LMA in difficult airway management is increasing as it can bypass obstruction at supraglottic level to provide rescue oxygenation and ventilation in patients with adequate mouth opening.[5,38]

The Ambu AuraGain is a second generation LMA which is anatomically curved to follow the human airway. It has gastric access, bite block and wide airway tube making it useful for ventilation and as a conduit for tracheal intubation. The presence of gastric drain port and thin, soft cuff provide a good seal with high sealing pressures preventing the risk of gastric regurgitation and aspiration.[9]

In our study, we assessed the feasibility of using auricle size as a tool to select appropriate size of LMA as an alternative to the traditional weight based method as the shape of the external ear is similar to the shape of cuff of the LMA. The success rate for LMA size selection and insertion based on auricle size and conventional weight based methods was comparable in our study. The auricle size based method could be an additional tool to the existing methods and may help the clinicians to avoid memorising weight or age based tables and formulas. Moreover this technique may be highly useful for emergency physicians, staff and medical technicians because they frequently use LMAs and do not have time to look at the weight based tables or other methods prior to LMA insertion. This method may also be useful in a failed intubation drill where time is a major concern.[16]

In our study, the two groups were comparable in terms of demographic data i.e. gender, age, BMI, height, weight, ASA grading and airway assessment. There were more female patients in both the groups which could be because our study population included more patients undergoing gynaecological procedures. The preoperative and intraoperative hemodynamic parameters i.e. heart rate, blood pressure were comparable in both the groups. No significant variation in intraoperative hemodynamic parameters were seen during the insertion of LMA.

In our study the successful placement of LMA in the first attempt was achieved in 95% with auricle size based estimation and 86.7% with the weight based method which was comparable in both the groups. Haliloglu et al saw the successful placement of auricle size based Proseal LMA in 90% patients. The authors concluded that weight based method overestimated the size of Proseal LMA.[5] In the study by Zahoor et al, the successful LMA insertion with pinna size method was 93%. They concluded in their study that the ear size based estimation underestimated the required LMA size and thus a half size larger LMA was chosen for adequate ventilation.[16] In a similar study by Ravi et al, the PLMA placement in the first attempt was 93.07% in pinna size based group which was comparable to our study.[39]

In our study, no female patient in pinna size based group required change in the size of LMA whereas 3 (18%) male patients required second attempt with a change of LMA size to one size bigger as the size estimation by pinna size resulted in smaller size of LMA selection. On the other hand, in 7(15%) female patients in the weight based group a smaller size LMA had to be inserted as the size of LMA determined by weight overestimated the LMA size while only 1(6%) male patient required a change to smaller size LMA. This could be because the mouth opening in the females was less in comparison to the males, hence the weight based method of selection of LMA was not appropriate. In the study by Ravi et al second attempt was required in 7% patients of pinna based group while second and third

attempt in 10% patients in weight based group.[39] In both the studies by Haliloglu et al and Zahoor et al change in LMA was done in 6% of the patients in pinna size based group which was similar to our study in which second attempt was done in 5% patients in the auricle size based group and 13% in the weight based group.[5,16] In contrast to our study, Uma Kamath et al. conducted the study in which more number of attempts for successful LMA placement were required in pinna based group (16%) than the weight based group (2%) and this was statistically significant.[38] This difference could be because their study included more male patients than females.

In our study, there was statistically significant difference in the OLP in both the groups with mean higher OLP in the weight based group. The mean OLP of auricle size based group was 24.6 cm H_2O and weight based group was 30.53 cm H_2O. OLP is indicative of degree of airway protection, feasibility of positive pressure ventilation and also the likelihood for successful placement of the LMA. It is one of the properties that determine the efficacy of SAD as the device which provides lower peak airway pressures with higher oropharyngeal leak pressures with effective ventilation is expected to have higher margin of safety. The preformed shape of Ambu AuraGain and larger size of the cuff may be responsible for better positioning and seal provided by the device.[9]

OLP should be greater than the pressure of fluid at the posterior pharyngeal wall which is approximately 10 cm of H_2O to prevent leakage of gas and aspiration of pharyngeal secretions.[5] OLP depends on the seal between the cuff and perilaryngeal tissues.[40] Thus higher the OLP, better is the prevention against gastric aspiration. As in our study, the OLP was higher with weight based method, the chances of aspiration are greater with auricle size based selection of the LMA. Contrary to our study, OLP in pinna group was 25.4 cm H_2O and weight based group was 24.9 cm H_2O in the study by Ravi et al and no significant difference was seen in both the groups.[39] In the study by Haliloglu et al OLP was 28.6 cm H_2O in

pinna based group which was higher than in our study.[5] These studies were done in pediatric patients and differences in the OLP probably reflects a difference in their anatomy with the pediatric airway.

Both the groups had comparable and high successful rates of insertion. The depth of anaesthesia required for LMA insertion can be achieved by the induction agent alone and generally does not require administration of muscle relaxants. Thus the dose of propofol should blunt the airway reflexes to prevent laryngospasm, cough or other hemodynamic complications. The use of muscle relaxants decreases the laryngeal and pharyngeal muscle tone increasing the relaxation of jaw. This facilitates proper placement of LMA over the glottis.[40] Nasseri K studied the effect of low dose atracurium on insertion of LMA comparing the ease of insertion in patients receiving placebo and atracurium. Low doses of atracurium increased jaw relaxation and facilitated LMA insertion. It also decreased the time for LMA insertion and post operative sore throat.[42] Higher doses of propofol causes hemodynamic instability, hence we used propofol with opioids and low dose atracurium to facilitate insertion of Ambu AuraGain in our study and observed high rates of successful LMA placement in both the groups. We used standard anaesthesia induction technique for both the groups and hence adequate plane of anaesthesia was maintained at the time of LMA insertion.

In our study, the mean insertion time in auricle size based group was 14.05 sec and in weight based group was 16.12 sec which was statistically significant with a p-value of 0.001 sec. This difference could be attributed to the fact that the size of LMA determined by the auricle method was less making it easier to insert. In the study by Haliloglu et al the insertion time was comparable in both the groups(15+-1.6 sec).[5] In another study by Marc Kriege et al the insertion time of Ambu AuraGain was higher (13-14 sec) compared to LMA supreme which could be related to the curved angle of Ambu AuraGain making it difficult to insert.[43]

Based on subjective judgement, the difficulty of insertion of Ambu AuraGain LMA in our study was graded as easy (73%) and moderate (27%) in auricle size based method and moderate (82%) to difficult (18%) in the weight based method which was statistically significant. This could be because the LMA size selection by auricle size based method was in proximity to the airway than the weight based method making it easier to insert. In the study by Ravi et al the insertion and placement of the LMA was easier and comparable in the two groups, the insertion being easy in 93% patients in pinna based group and 90% in the weight based group.[39] The LMA used in this study was different from our study as they used Proseal LMA. In the previous studies as well, the ease of insertion of Ambu AuraGain LMA was generally rated as moderate or difficult.[43] It has different shape of the tip and is rigid which makes its initial placement more challenging.

There was no insertion failure in both the groups in our study. The respiratory parameters such as the tidal volume and the peak airway pressures generated were also comparable in both the groups.

Post-operative complications such as dental injury, blood staining and dysphonia were noted in our study. The incidence of these complications were higher in weight based group. Dental injury was seen in 5% patients, blood staining in 50% patients and dysphonia in 32% patients. This could be because of the larger size of the LMA in relation to their anatomical structures used in the patients. In contrast to this, no traumatic insertion was seen in any of the two groups in the study by Ravi et al.[39] In a study by Mark Kreige, the incidence of airway complications was higher in Ambu AuraGain as compared to LMA Supreme.[43]

The post-operative sore throat was graded by Numeric Rating Scale (NRS) in post anaesthesia care unit (PACU) by the patient. A score of 4 or more was considered as indicative of sore throat.[41] In our study, none of the patients complained of sore throat in the auricle size based group whereas 70% patients complained of sore throat in the weight

based group which self resolved in few hours. This was in contrast to the study by Ravi et al in which none patients had sore throat in the post-operative period.[39] The larger cuff of the LMA in comparison to the pharyngeal mucosa could have resulted in the pressure on the mucosa in the perilaryngeal structures resulting in sore throat in the patients.

The causes for trauma of upper airway with LMA are repeated insertion attempts with inadequate anaesthesia, limited experience with the LMA and inexperienced anaesthesiologist. Also high cuff pressures can reduce pharyngeal mucosal perfusion causing airway complications. All these factors were comparable in our study in both the groups. The type and duration of surgery did not influence the incidence of upper airway morbidity and complications.[43]

There were certain limitations in our study. Blinding was not possible for the technique of LMA size selection. Patients less than 18 years of age were not included in our study. We did not use fibreoptic bronchoscope to grade the glottis view for appropriate placement of the LMA but instead relied on other clinical factors. Moreover LMA was inserted by experienced anaesthesiologist and may not be applicable to the ones with lesser experience.

In conclusion, the auricle size based estimation of LMA size selection can be used as an alternative to weight based method in emergency situations.

SUMMARY AND CONCLUSIONS

The study was conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after getting approval from the Institutional ethics committee. We compared auricle size based method with weight based method for selection of optimal size of AuraGain laryngeal mask airway in adults.

One hundred and twenty ASA I-III adults scheduled for elective surgeries under general anaesthesia in supine position were studied in a prospective, randomised, interventional trial after obtaining a written informed consent. The patients were randomly allocated into two groups of 60 patients each using computer generated random numbers.

Group A: Ambu AuraGain LMA size was selected by measuring the size of the auricle with a ruler in the vertical and horizontal dimensions in cms.

Group B: Ambu AuraGain LMA size was selected based on patients' weight as per the manufacturer's guidelines.

The LMA was inserted by experienced anaesthesiologist after adequate plane of anaesthesia was achieved.

Patients were assessed for successful LMA placement in first attempt, OLP, time of insertion of Ambu AuraGain, difficulty of insertion and post-operative complications if any. Results were analysed statistically.

We observed that the mean oropharyngeal leak pressure (24.60+-2.53 versus 30.53+-1.80 cm H_2O, p-value 0.001) and the mean time of insertion (14.05+-1.97 versus 16.12+-2.50 secs) were statistically significant.

The larger size mask in the weight based method lead to higher OLP, hence providing safety in ventilation. We can select the LMA size by auricle size method for short surgical procedures.

The weight based method for LMA size selection would not be accurate for females (obese and smaller facial structures) as compared to males.

The size of the cuff of LMA according to weight based method lead to more post-operative sore throat in comparison to auricle size based method.

Hence we conclude that auricle size based estimation of LMA size selection can be used as an alternative to the traditional weight based method in emergency situations.

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DEPARTMENT OF ANAESTHESIOLOGY

DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA

PROFORMA

Sr. Number: Group: Technique of size selection:

MRD Number: Date of surgery:

Duration of surgery:

DEMOGRAPHIC DATA

Age and Sex: ASA grade:

Height (cm): Nutritional status:

Weight (kg): BMI:

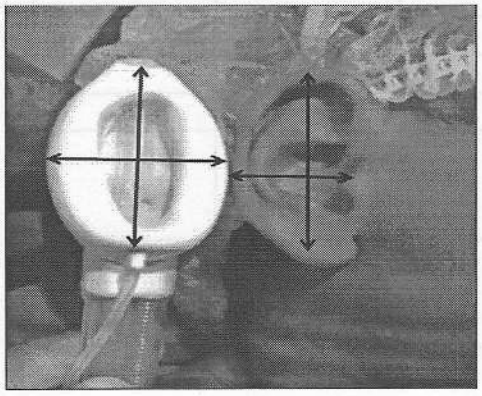
Mallampati score: Range of neck movement:

Edentulous: Thyromental distance:

Maximal interdental distance: Neck circumference:

Overbite test: Sternomental distance:

AURICLE DIMENSIONS



VERTICAL (cm):

HORIZONTAL (cm):

SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

SIZE OF AURA LMA INSERTED

	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5
Vertical(cm)	6.5	8	9	10
Horizontal(cm)	4	5.5	5.75	6.25

HAEMODYNAMIC PARAMETERS

Vitals	HR (/min)	SBP (mmHg)	DBP (mmHg)	Mean BP(mmHg)	SPO_2 (%)
Baseline					
Induction					
1 min					
2 min					
3 min					
4 min					
5 min					
Till successful placement of the device					
After successful placement of the device					

RESPIRATORY PARAMETERS

Vitals	Expired Tidal Volume	Peak Pressure	Plateau Pressure	$EtCO_2$ (mmHg)
Baseline				
Induction				
1 min				
2 min				
3 min				
4 min				
5 min				
Till successful placement of the device				
After successful placement of the device				

SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

CRITERIA FOR SUCCESSFUL PLACEMENT

Parameter		YES	NO
Visible chest rise			
Bilaterally equal chest auscultation			
Appearance of a square waveform $EtCO_2$			
Oral leak pressure >10mm Hg	_____mm Hg		

Successful placement: Yes/No

Successful placement in first attempt: Yes/No

Insertion attempts:

Insertion time:

Any change in the size of device required: YES / NO

If yes, Size of the device:

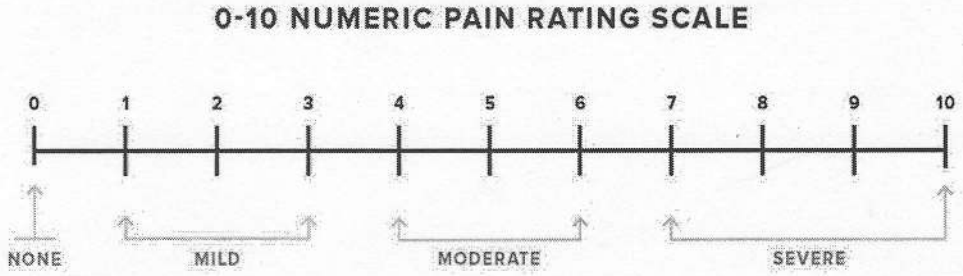
DIFFICULTY OF INSERTION .

1) Easy	2) moderate	3) difficult	4) impossible

COMPLICATIONS

		YES	NO
Desaturation episodes (SpO_2 less than 90%)	Number of episodes: ____		
Dental injury			
Blood staining			
Dysphagia			
Dysphonia			

SORE THROAT



SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

KEY TO MASTER CHART

Cm	Centimetre
Kg	Kilogram
ASA	American society of Anaesthesiologist
BMI	Body mass index
LMA	Laryngeal mask airway
HR	Heart rate
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
SpO2	Arterial oxyhemoglobin saturation
ETCO2	End tidal carbon dioxide
H2O	Water

Sr NO	MRD Number	Group	Date of surgery	Duration of surgery	Age and Sex	Height (cm)	Weight (kg)	Mallampati score	ASA Grade	BMI	Neck movements	Thyromental distance	Sternomental distance	Neck circumference	Auricle dimensions		Size of Aura LMA inserted
																Horizontal (cm)	
1	1282700	B	06/04/22	120 MIN	43y/M	172	78	III	I	25.7	ADEQUATE	>6.5CM	>12.5CM	35	-	-	5
2	3511	A	18/05/22	40 MIN	58y/M	172	70	I	III	23.7	ADEQUATE	>6.5CM	>12.5CM	34	7.1	3.6	3
3	1306238	A	24/05/22	60 MIN	34y/F	162	50	II	I	19.1	ADEQUATE	>6.5CM	>12.5CM	28	6	3	2.5
4	969909	A	10/08/21	40 MIN	36Y/F	157	65	II	I	26.4	ADEQUATE	>6.5CM	>12.5CM	33	6.6	3.1	3
5	1256892	B	02/04/22	60 MIN	28Y/F	159	50	I	I	19.8	ADEQUATE	>6.5CM	>12.5CM	28	-	-	3
6	1263247	B	04/04/22	75 MIN	40Y/F	162	65	III	II	24.8	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
7	1306681	A	21/05/22	50 MIN	38Y/F	158	68	II	II	27.2	ADEQUATE	>6.5CM	>12.5CM	34	6.7	3.2	3
8	1272466	B	17/05/22	45 MIN	42Y/F	154	67	III	I	28.3	ADEQUATE	>6.5CM	>12.5CM	35	-	-	4
9	47453	B	17/05/22	70 MIN	65Y/F	167	82	III	III	29.4	RESTRICTED	>6.5CM	>12.5CM	39	-	-	5
10	1282311	A	05/04/22	75 MIN	35Y/F	154	64	II	II	27	ADEQUATE	>6.5CM	>12.5CM	33	6.6	3.1	3
11	1266976	B	06/04/22	90 MIN	39Y/F	152	51	II	I	22.1	ADEQUATE	>6.5CM	>12.5CM	30	-	-	4
12	1259845	B	06/04/22	45 MIN	32Y/F	165	91	II	I	33.4	ADEQUATE	>6.5CM	>12.5CM	39	-	-	5
13	793805	A	29/11/21	30 MIN	30Y/F	160	73	II	III	28.5	ADEQUATE	>6.5CM	>12.5CM	36	6.6	3	3
14	1170016	B	15/09/21	100 MIN	30Y/M	160	65	II	I	25.4	ADEQUATE	>6.5CM	>12.5CM	35	-	-	4
15	1214248	A	27/01/22	45 MIN	40Y/F	158	52	I	I	20.8	ADEQUATE	>6.5CM	>12.5CM	34	6.7	3.2	3
16	1244444	B	28/01/22	50 MIN	39Y/F	152	68	I	II	29.4	ADEQUATE	>6.5CM	>12.5CM	35	-	-	4
17	1240054	B	17/01/22	60 MIN	48Y/M	170	80	II	I	27.7	ADEQUATE	>6.5CM	>12.5CM	38	-	-	5
18	1241046	B	19/01/22	30 MIN	32Y/F	157	45	I	I	18.3	ADEQUATE	>6.5CM	>12.5CM	33	-	-	3
19	1236175	B	15/01/22	120 MIN	25Y/F	160	58	I	II	22.7	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
20	1245170	A	28/01/22	40 MIN	55Y/F	160	64	I	I	25	ADEQUATE	>6.5CM	>12.5CM	33	6.7	3.1	3
21	1231624	B	03/01/22	60 MIN	56Y/F	160	70	II	I	27.3	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
22	1198976	B	19/01/22	40 MIN	45Y/F	159	60	I	I	23.7	ADEQUATE	>6.5CM	>12.5CM	36	-	-	4
23	1241675	A	20/01/22	150 MIN	34Y/M	170	75	II	II	26	ADEQUATE	>6.5CM	>12.5CM	36	7.1	4	3
24	1244585	B	05/02/22	35 MIN	52Y/F	156	65	II	I	26.7	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
25	1249420	B	16/02/22	120 MIN	43Y/F	157	56	I	III	22.7	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
26	1198562	B	26/02/22	65 MIN	21Y/M	175	80	I	I	26.1	ADEQUATE	>6.5CM	>12.5CM	34	-	-	5
27	1259092	A	01/03/22	40 MIN	30Y/F	155	50	I	I	20.8	ADEQUATE	>6.5CM	>12.5CM	28	6.1	3	2.5
28	1259655	B	01/03/22	35 MIN	44Y/F	158	56	II	I	22.4	ADEQUATE	>6.5CM	>12.5CM	31	-	-	4
29	8533	A	01/03/22	60 MIN	35Y/F	166	58	II	I	21	ADEQUATE	>6.5CM	>12.5CM	30	6.8	3.4	3
30	1261678	B	02/03/22	35 MIN	45Y/F	164	64	II	I	23.8	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
31	1262146	A	02/03/22	30 MIN	45Y/F	160	66	II	I	25.8	ADEQUATE	>6.5CM	>12.5CM	33	6.8	3.2	3
32	1263648	A	05/03/22	30 MIN	32Y/F	163	60	II	I	22.6	ADEQUATE	>6.5CM	>12.5CM	30	6.7	3.4	3
33	1264028	A	07/03/22	25 MIN	27Y/F	154	41	II	I	17.3	ADEQUATE	>6.5CM	>12.5CM	28	6.2	3.1	2.5
34	12647232	B	07/03/22	20 MIN	38Y/F	160	60	II	I	23.4	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
35	1262939	B	07/03/22	30 MIN	41Y/F	162	61	III	I	23.2	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
36	1086168	B	08/03/22	40 MIN	22Y/F	155	43	I	I	17.9	ADEQUATE	>6.5CM	>12.5CM	27	-	-	3
37	1226117	B	12/03/22	75 MIN	49Y/M	167	55	II	II	19.7	ADEQUATE	>6.5CM	>12.5CM	30	-	-	4
38	1267043	B	14/03/22	40 MIN	18Y/F	156	45	I	I	18.5	ADEQUATE	>6.5CM	>12.5CM	26	-	-	3
39	1268890	A	14/03/22	30 MIN	30Y/F	159	65	II	I	25.7	ADEQUATE	>6.5CM	>12.5CM	33	6.6	3	3
40	887869	A	15/03/22	35 MIN	33Y/F	159	63	III	I	24.9	ADEQUATE	>6.5CM	>12.5CM	32	6.7	3.1	3
41	1219604	B	17/03/22	20 MIN	34Y/F	150	48	III	I	21.3	ADEQUATE	>6.5CM	>12.5CM	29	-	-	3

Sr NO	MRD Number	HR(/min)		SBP(mmHg)		DBP(mmHg)		SpO2		ETCO2	Expired Tidal Volume	Peak Pressure	Plateau Pressure	Visible chest rise	Bilaterally equal chest auscultation	Appearance of a square waveform EtCO2
		Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device							
1	1282700	88	86	130	124	80	76	97%	100%	32	500	18	16	Y	Y	Y
2	3511	82	90	130	124	80	76	97%	99%	31	450	18	15	Y	Y	Y
3	1306238	86	92	130	124	70	74	100%	100%	31	430	17	15	Y	Y	Y
4	969909	100	94	100	108	70	72	98%	100%	33	420	17	15	Y	Y	Y
5	1256892	90	96	100	110	60	70	98%	99%	33	400	15	13	Y	Y	Y
6	1263247	68	78	110	120	70	74	99%	99%	33	460	16	15	Y	Y	Y
7	1306681	82	90	130	126	80	82	98%	99%	34	450	17	17	Y	Y	Y
8	1272466	84	92	100	116	70	76	97%	99%	31	500	20	19	Y	Y	Y
9	47453	68	86	130	124	70	72	97%	99%	32	420	15	15	N	N	N
10	1282311	108	104	110	114	70	72	98%	100%	30	500	18	17	Y	Y	Y
11	1266976	80	82	120	122	60	64	98%	99%	31	480	15	15	Y	Y	Y
12	1259845	80	76	110	114	70	70	97%	100%	31	500	18	17	N	N	N
13	793805	86	92	110	118	70	80	97%	99%	32	430	15	12	Y	Y	Y
14	1170016	68	80	100	108	70	72	98%	99%	33	420	15	12	Y	Y	Y
15	1214248	70	78	104	108	60	72	97%	99%	30	400	14	12	Y	Y	Y
16	1244444	78	86	110	118	68	72	98%	99%	33	450	18	16	Y	Y	Y
17	1240054	124	98	140	136	88	76	99%	100%	34	500	13	11	Y	Y	Y
18	1241046	110	96	110	118	70	74	100%	100%	32	380	12	10	Y	Y	Y
19	1236175	130	104	110	124	60	68	99%	99%	34	430	14	13	Y	Y	Y
20	1245170	96	88	100	120	60	70	97%	99%	32	430	14	12	Y	Y	Y
21	1231624	80	92	140	128	80	74	99%	100%	34	500	18	13	Y	Y	Y
22	1198976	88	80	140	126	82	76	99%	100%	32	450	12	11	Y	Y	Y
23	1241675	84	78	132	126	88	82	97%	98%	33	500	21	14	Y	Y	Y
24	1244585	72	78	110	108	70	62	98%	99%	33	420	18	16	Y	Y	Y
25	1249420	86	94	100	108	70	78	98%	100%	36	400	15	14	Y	Y	Y
26	1198562	110	104	130	122	90	80	98%	99%	33	500	13	12	Y	Y	Y
27	1259092	98	106	110	100	70	68	97%	99%	32	450	13	12	Y	Y	Y
28	1259655	70	88	100	108	60	72	98%	99%	30	400	12	11	Y	Y	Y
29	8533	88	92	100	110	60	68	97%	99%	30	430	17	16	Y	Y	Y
30	1261678	88	90	120	112	90	76	97%	99%	30	420	12	11	Y	Y	Y
31	1262146	88	94	110	116	70	78	99%	100%	30	450	12	12	Y	Y	Y
32	1263648	80	84	110	122	60	74	97%	100%	32	420	15	14	Y	Y	Y
33	1264028	98	106	100	96	70	62	99%	100%	34	350	12	10	Y	Y	Y
34	12647232	88	82	112	122	64	68	99%	100%	29	430	13	12	Y	Y	Y
35	1262939	82	88	140	128	90	86	99%	100%	30	460	15	14	Y	Y	Y
36	1086168	86	94	100	106	70	62	99%	100%	34	350	14	13	Y	Y	Y
37	1226117	96	108	110	122	70	72	96%	99%	30	450	15	13	Y	Y	Y
38	1267043	90	98	100	104	70	68	100%	100%	30	400	10	10	Y	Y	Y
39	1268890	88	82	110	114	70	76	99%	100%	32	440	17	15	Y	Y	Y
40	887869	92	90	100	108	60	72	98%	99%	31	430	12	11	Y	Y	Y
41	1219604	72	88	110	104	70	68	98%	100%	29	400	11	10	Y	Y	Y

Sr NO	MRD Number	Oral leak pressure >10cm H_2O	Successful placement	Successful placement in first attempt	Insertion attempts	Insertion time	Any change in the size of device required If yes, size of the device	Difficulty of insertion	Desaturation episodes	Dental injury	Blood staining	Dysphagia	Dysphonia	Sore throat rating scale
1	1282700	33	Y	Y	1	16	N	DIFFICULT	N	N	Y	N	Y	5
2	3511	22	Y	Y	1	11	N	EASY	N	N	N	N	N	1
3	1306238	22	Y	Y	1	13	**N**	EASY	N	N	N	N	N	2
4	969909	26	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
5	1256892	30	Y	Y	1	12	**N**	MODERATE	N	N	N	N	N	3
6	1263247	32	Y	Y	1	14	**N**	MODERATE	N	N	N	N	Y	4
7	1306681	27	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
8	1272466	32	Y	Y	1	13	**N**	MODERATE	N	N	N	N	Y	4
9	47453	33	N	N	2	16	**Y/4**	DIFFICULT	N	N	Y	N	Y	5
10	1282311	26	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
11	1266976	32	Y	Y	1	15	**N**	DIFFICULT	N	N	Y	N	Y	5
12	1259845	33	N	N	2	22	**Y/4**	DIFFICULT	N	N	Y	N	Y	5
13	793805	22	Y	Y	1	11	**N**	EASY	N	N	N	N	N	1
14	1170016	24	Y	Y	1	12	**N**	MODERATE	N	N	N	N	N	3
15	1214248	28	Y	Y	1	13	**N**	EASY	N	N	N	N	N	1
16	1244444	32	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	2
17	1240054	32	Y	Y	1	14	**N**	MODERATE	N	N	N	N	Y	4
18	1241046	30	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	3
19	1236175	32	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	4
20	1245170	26	Y	Y	1	12	**N**	EASY	N	N	N	N	N	1
21	1231624	28	Y	Y	1	13	**N**	MODERATE	N	N	N	N	N	3
22	1198976	32	Y	Y	1	13	**N**	MODERATE	N	N	N	N	N	2
23	1241675	22	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
24	1244585	29	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	3
25	1249420	30	Y	Y	1	15	**N**	MODERATE	N	N	Y	N	N	5
26	1198562	32	Y	Y	1	16	**N**	DIFFICULT	N	N	Y	N	Y	5
27	1259092	22	Y	Y	1	12	**N**	EASY	N	N	N	N	N	1
28	1259655	32	Y	Y	1	17	**N**	DIFFICULT	N	N	Y	N	Y	5
29	8533	26	Y	Y	1	13	**N**	EASY	N	N	N	N	N	2
30	1261678	28	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	3
31	1262146	23	Y	Y	1	13	**N**	EASY	N	N	N	N	N	2
32	1263648	26	Y	Y	1	13	**N**	MODERATE	N	N	N	N	N	2
33	1264028	23	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
34	12647232	29	Y	Y	1	16	**N**	MODERATE	N	N	N	N	Y	4
35	1262939	31	Y	Y	1	17	**N**	DIFFICULT	N	Y	Y	N	Y	5
36	1086168	27	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	3
37	1226117	29	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
38	1267043	32	Y	Y	1	16	**N**	DIFFICULT	N	N	Y	N	Y	5
39	1268890	26	Y	Y	1	13	**N**	EASY	N	N	N	N	N	1
40	887869	25	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	2
41	1219604	28	Y	Y	1	18	**N**	DIFFICULT	N	N	Y	N	Y	5

Sr NO	MRD Number	Group	Date of surgery	Duration of surgery	Age and Sex	Height (cm)	Weight (kg)	Mallampati score	ASA Grade	BMI	Neck movements	Thyromental distance	Sternomental distance	Neck circumference	Auricle dimensions		Size of Aura LMA inserted
																Horizontal (cm)	
42	759387	A	17/03/22	25 MIN	33Y/F	157	64	II	I	26	ADEQUATE	>6.5CM	>12.5CM	33	6.7	3.4	3
43	1271841	B	19/03/22	45 MIN	33Y/F	165	67	II	I	24.6	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
44	1100716	A	19/03/22	50 MIN	43Y/F	158	78	II	II	31.2	ADEQUATE	>6.5CM	>12.5CM	36	6.8	3.4	3
45	1271269	B	19/03/22	40 MIN	44Y/F	160	58	I	I	22.7	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
46	331896	A	21/03/22	25 MIN	34Y/F	147	62	II	II	28.5	ADEQUATE	>6.5CM	>12.5CM	34.5	6.1	3	2.5
47	753587	B	21/03/22	35 MIN	26Y/F	155	70	I	I	29.5	ADEQUATE	>6.5CM	>12.5CM	36	-	-	4
48	1282311	A	05/04/22	90 MIN	35Y/F	159	55	II	I	21.8	ADEQUATE	>6.5CM	>12.5CM	28	6.6	3.2	3
49	1282363	B	08/04/22	75 MIN	35Y/F	156	50	I	I	21.3	ADEQUATE	>6.5CM	>12.5CM	29.5	-	-	3
50	1270812	A	09/04/22	30 MIN	43Y/M	160	76	II	I	28.8	ADEQUATE	>6.5CM	>12.5CM	36	6.9	3.8	3
51	1007672	B	09/04/22	30 MIN	31Y/F	157	54	II	I	22	ADEQUATE	>6.5CM	>12.5CM	31	-	-	4
52	1279544	B	12/04/22	90 MIN	40Y/F	160	60	II	I	23.4	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
53	1280340	B	13/04/22	45 MIN	66Y/M	172	100	II	III	33.5	RESTRICTED	6CM	11CM	42	-	-	5
54	962352	A	13/04/22	120 MIN	25Y/F	156	52	II	I	21.4	ADEQUATE	>6.5CM	>12.5CM	30	6.8	3.5	3
55	490977	A	03/05/22	150MIN	69Y/F	157	80	II	II	32.2	RESTRICTED	>6.5CM	>12.5CM	38	6.9	3.2	3
56	1290121	A	11/05/22	50 MIN	52Y/M	162	76	II	III	29	ADEQUATE	>6.5CM	>12.5CM	36	7	3.6	3
57	1151762	A	11/05/22	25 MIN	33Y/M	172	78	II	I	26.4	ADEQUATE	>6.5CM	>12.5CM	33	7.1	3.7	3
58	1319998	B	13/06/22	150 MIN	25Y/F	154	60	I	I	25.3	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
59	1321713	A	13/06/22	60 MIN	58Y/M	167	71	IV	III	25.3	RESTRICTED	>6.5CM	>12.5CM	33	7.2	3.7	3
60	1320477	A	14/06/22	75 MIN	33Y/M	172	77	I	III	26	ADEQUATE	>6.5CM	>12.5CM	35	7.1	3.8	3
61	1139641	B	20/07/21	30 MIN	57Y/F	165	76	III	I	27.9	RESTRICTED	>6.5CM	>12.5CM	34	-	-	5
62	1139624	A	20/07/21	30 MIN	27Y/F	157	54	III	II	21.9	ADEQUATE	>6.5CM	>12.5CM	30	6.3	3.1	2.5
63	1142302	B	24/07/21	50 MIN	38Y/M	172	70	I	I	24	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
64	1171754	B	12/09/21	60 MIN	39Y/F	152	68	II	I	29.4	ADEQUATE	>6.5CM	>12.5CM	36	-	-	4
65	1029445	B	13/09/21	70 MIN	25Y/M	172	70	I	I	23.7	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
66	432987	B	19/01/22	45 MIN	29Y/F	159	49	II	I	19.4	ADEQUATE	>6.5CM	>12.5CM	33	-	-	3
67	1271269	A	19/03/22	40 MIN	44Y/F	160	58	I	I	22.7	ADEQUATE	>6.5CM	>12.5CM	31	6.3	3.1	2.5
68	1272138	A	21/03/22	25 MIN	32Y/F	162	83	II	I	32.4	ADEQUATE	>6.5CM	>12.5CM	38	6.7	3.4	3
69	1278248	A	30/03/22	30 MIN	50Y/F	157	76	III	I	30.8	ADEQUATE	>6.5CM	>12.5CM	36	6.7	3.4	3
70	1296235	A	02/05/22	60 MIN	30Y/F	162	58	II	I	22.1	ADEQUATE	>6.5CM	>12.5CM	35	6.6	3.5	3
71	1296473	A	02/05/22	75 MIN	38Y/M	162	77	III	I	29.1	ADEQUATE	>6.5CM	>12.5CM	35.5	7.1	3.8	3
72	1299669	A	11/05/22	30 MIN	47Y/M	170	80	II	I	27.7	ADEQUATE	>6.5CM	>12.5CM	35	7.1	3.7	3
73	1154961	B	14/05/22	20 MIN	36Y/M	170	86	II	I	29.8	ADEQUATE	>6.5CM	>12.5CM	39	-	-	5
74	1322190	A	14/06/22	60 MIN	32Y/F	164	55	III	I	20.4	ADEQUATE	>6.5CM	>12.5CM	29	6.1	3.1	2.5
75	1321840	B	14/06/22	30 MIN	48Y/F	157	74	II	I	29	ADEQUATE	>6.5CM	>12.5CM	36	-	-	5
76	1320196	A	14/06/22	120 MIN	57Y/F	157	60	I	II	24.3	ADEQUATE	>6.5CM	>12.5CM	34	6.7	3.3	3
77	1313307	B	16/06/22	120 MIN	32Y/M	180	100	III	II	30.9	RESTRICTED	6CM	11.5CM	40	-	-	5
78	1323722	A	16/06/22	90 MIN	28Y/F	162	60	II	I	26.3	ADEQUATE	>6.5CM	>12.5CM	33	6.4	3.2	2.5
79	1294290	B	16/06/22	120 MIN	52Y/M	180	105	III	II	32.3	RESTRICTED	>6.5CM	>12.5CM	43	-	-	5
80	1263866	A	16/06/22	60 MIN	51Y/M	167	90	II	III	32.3	RESTRICTED	>6.5CM	>12.5CM	43	7.2	3.8	3
81	1323641	B	18/06/22	60 MIN	27Y/F	167	75	III	I	26.9	ADEQUATE	>6.5CM	>12.5CM	33	-	-	5
82	1002528	A	18/06/22	60 MIN	18Y/M	170	60	I	I	18.7	ADEQUATE	>6.5CM	>12.5CM	27	7.1	3.4	3

Sr NO	MRD Number	HR(/min)		SBP(mmHg)		DBP(mmHg)		SpO2		ETCO2	Expired Tidal Volume	Peak Pressure	Plateau Pressure	Visible chest rise	Bilaterally equal chest auscultation	Appearance of a square waveform EtCO2
		Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device							
42	759387	100	104	100	110	60	76	97%	99%	32	420	13	11	Y	Y	Y
43	1271841	76	90	130	118	80	76	97%	100%	30	460	10	10	Y	Y	Y
44	1100716	82	90	120	114	90	82	98%	100%	34	400	14	13	Y	Y	Y
45	1271269	78	92	110	118	70	78	98%	99%	31	400	11	11	Y	Y	Y
46	331896	98	88	110	124	70	70	100%	100%	32	420	16	14	Y	Y	Y
47	753587	80	86	120	124	80	78	98%	99%	31	420	15	12	Y	Y	Y
48	1282311	82	90	110	106	80	74	98%	100%	33	420	17	15	Y	Y	Y
49	1282363	80	86	120	116	70	68	100%	100%	29	380	15	14	Y	Y	Y
50	1270812	88	82	110	114	80	74	97%	99%	32	450	12	10	Y	Y	Y
51	1007672	84	88	110	104	70	68	98%	100%	34	380	17	16	Y	Y	Y
52	1279544	80	94	120	108	70	64	98%	99%	31	450	15	14	Y	Y	Y
53	1280340	80	96	130	122	80	68	97%	99%	33	510	12	11	Y	Y	Y
54	962352	84	90	110	106	70	72	100%	100%	35	420	10	10	Y	Y	Y
55	490977	80	92	180	162	90	82	98%	99%	33	450	20	18	Y	Y	Y
56	1290121	88	82	140	128	92	94	98%	99%	34	450	18	15	Y	Y	Y
57	1151762	78	82	130	118	76	72	99%	100%	33	500	18	15	N	N	N
58	1319998	82	78	110	116	70	80	97%	99%	33	450	18	16	Y	Y	Y
59	1321713	80	88	114	110	64	70	97%	98%	34	490	17	15	Y	Y	Y
60	1320477	84	92	130	124	80	82	98%	100%	30	480	13	12	Y	Y	Y
61	1139641	82	98	130	126	90	80	98%	99%	33	440	13	12	N	N	N
62	1139624	96	104	104	100	68	62	96%	98%	31	400	12	11	Y	Y	Y
63	1142302	88	94	120	112	70	62	98%	100%	30	450	10	9	Y	Y	Y
64	1171754	78	86	100	108	70	68	98%	99%	30	450	17	16	Y	Y	Y
65	1029445	74	86	112	108	70	72	99%	100%	33	480	14	13	Y	Y	Y
66	432987	100	90	100	108	60	76	97%	99%	31	420	12	11	Y	Y	Y
67	1271269	82	90	110	102	74	68	99%	100%	33	440	14	12	Y	Y	Y
68	1272138	88	96	126	108	78	64	98%	99%	35	450	16	15	Y	Y	Y
69	1278248	76	88	130	118	90	78	97%	99%	34	450	15	14	Y	Y	Y
70	1296235	82	94	124	112	78	68	97%	99%	31	450	12	10	Y	Y	Y
71	1296473	70	82	140	126	70	86	99%	100%	34	520	15	13	Y	Y	Y
72	1299669	94	90	110	104	70	66	99%	100%	31	490	14	14	N	N	N
73	1154961	70	84	120	112	70	64	98%	99%	32	500	20	17	Y	Y	Y
74	1322190	88	96	120	112	80	74	98%	99%	30	480	14	13	Y	Y	Y
75	1321840	102	110	110	118	60	74	98%	99%	32	450	15	13	N	N	N
76	1320196	94	90	160	138	80	72	98%	99%	31	420	20	19	Y	Y	Y
77	1313307	74	88	120	112	60	72	98%	99%	30	520	16	14	Y	Y	Y
78	1323722	80	96	120	112	70	64	98%	100%	35	410	20	18	Y	Y	Y
79	1294290	98	92	110	118	68	74	97%	99%	35	500	18	16	Y	Y	Y
80	1263866	64	82	110	102	60	68	99%	99%	34	450	14	13	N	N	N
81	1323641	88	102	114	102	72	66	99%	100%	32	440	15	13	N	N	N
82	1002528	82	94	116	108	68	64	99%	100%	33	480	13	12	Y	Y	Y

Sr NO	MRD Number	Oral leak pressure >10cm H_2O	Successful placement	Successful placement in first attempt	Insertion attempts	Insertion time	Any change in the size of device required If yes, size of the device	Difficulty of insertion	Desaturation episodes	Dental injury	Blood staining	Dysphagia	Dysphonia	Sore throat rating scale
42	759387	24	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	2
43	1271841	29	Y	Y	1	16	**N**	MODERATE	N	N	Y	N	Y	5
44	1100716	22	Y	Y	1	15	**N**	EASY	N	N	N	N	N	3
45	1271269	29	Y	Y	1	17	**N**	DIFFICULT	N	Y	Y	N	N	5
46	331896	23	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
47	753587	28	Y	Y	1	13	**N**	MODERATE	N	N	Y	N	N	4
48	1282311	25	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	3
49	1282363	28	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	3
50	1270812	22	Y	Y	1	13	**N**	EASY	N	N	N	N	N	2
51	1007672	31	Y	Y	1	16	**N**	MODERATE	N	N	Y	N	N	4
52	1279544	30	Y	Y	1	16	**N**	MODERATE	N	N	Y	N	N	4
53	1280340	32	Y	Y	1	16	**N**	MODERATE	N	N	Y	N	Y	5
54	962352	28	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	3
55	490977	22	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
56	1290121	23	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
57	1151762	29	N	N	2	20	**Y/4**	MODERATE	N	N	Y	N	N	3
58	1319998	31	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	Y	5
59	1321713	22	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
60	1320477	18	Y	Y	1	14	**N**	EASY	N	N	N	N	N	1
61	1139641	32	N	N	2	22	**Y/4**	MODERATE	N	N	Y	N	Y	5
62	1139624	22	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
63	1142302	28	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	3
64	1171754	32	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	5
65	1029445	29	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	4
66	432987	31	Y	Y	1	13	**N**	MODERATE	N	N	N	N	N	3
67	1271269	24	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
68	1272138	22	Y	Y	1	11	**N**	EASY	N	N	N	N	N	2
69	1278248	22	Y	Y	1	13	**N**	MODERATE	N	N	N	N	N	2
70	1296235	28	Y	Y	1	12	**N**	EASY	N	N	N	N	N	2
71	1296473	24	Y	Y	1	14	**N**	EASY	N	N	N	N	N	3
72	1299669	29	N	N	2	20	**Y/4**	MODERATE	N	N	N	N	N	3
73	1154961	32	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	5
74	1322190	25	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
75	1321840	28	N	N	2	18	**Y/4**	DIFFICULT	N	Y	Y	N	Y	5
76	1320196	27	Y	Y	1	15	**N**	EASY	N	N	N	N	N	3
77	1313307	31	Y	Y	1	16	**N**	MODERATE	N	N	Y	N	N	4
78	1323722	23	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
79	1294290	30	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	4
80	1263866	27	N	N	2	21	**Y/4**	MODERATE	N	N	N	N	N	3
81	1323641	32	N	N	2	22	**Y/4**	MODERATE	N	N	Y	N	Y	5
82	1002528	27	Y	Y	1	16	**N**	EASY	N	N	N	N	N	3

Sr NO	MRD Number	Group	Date of surgery	Duration of surgery	Age and Sex	Height (cm)	Weight (kg)	Mallampati score	ASA Grade	BMI	Neck movements	Thyromental distance	Sternomental distance	Neck circumference	Auricle dimensions		Size of Aura LMA inserted
																Horizontal (cm)	
83	1325523	A	21/06/22	90 MIN	50Y/F	160	74	II	II	28.9	ADEQUATE	>6.5CM	>12.5CM	35	6.8	3.4	3
84	1326981	A	21/06/22	95 MIN	50Y/F	163	79	III	II	29.7	ADEQUATE	>6.5CM	>12.5CM	35	6.8	3.4	3
85	1328083	A	23/06/22	75 MIN	26Y/F	157	52	II	II	21.1	ADEQUATE	>6.5CM	>12.5CM	28	6.1	3.1	2.5
86	413751	B	23/06/22	90 MIN	21Y/F	162	65	I	I	24.8	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
87	1327498	A	26/06/22	90 MIN	80Y/F	162	85	III	III	32.4	RESTRICTED	6CM	11.5CM	38	6.9	3.8	3
88	1330386	B	27/06/22	90 MIN	20Y/M	162	87	III	II	33.2	ADEQUATE	>6.5CM	>12.5CM	41	-	-	5
89	1139609	A	23/07/22	75 MIN	24Y/F	158	80	II	I	32	ADEQUATE	>6.5CM	>12.5CM	38	6.7	3.2	3
90	1146332	A	13/09/21	35 MIN	53Y/M	164	70	III	I	26	ADEQUATE	>6.5CM	>12.5CM	33	7.2	3.5	3
91	1129447	A	04/07/21	40 MIN	52Y/M	170	52	I	II	18.5	ADEQUATE	>6.5CM	>12.5CM	28	7.2	3.4	3
92	1133270	B	08/07/21	35 MIN	47Y/F	157	85	II	III	34.5	ADEQUATE	>6.5CM	>12.5CM	40	-	-	5
93	952978	B	12/07/21	45 MIN	38Y/M	176	83	II	I	26.8	ADEQUATE	>6.5CM	>12.5CM	33	-	-	5
94	1136161	A	14/07/21	25 MIN	30Y/F	161	60	II	I	23.1	ADEQUATE	>6.5CM	>12.5CM	32	6.6	3	3
95	1170016	B	15/09/21	70 MIN	30Y/M	175	65	II	I	21.2	ADEQUATE	>6.5CM	>12.5CM	28	-	-	4
96	1184655	A	05/10/21	50 MIN	23Y/F	157	57	II	I	23.1	ADEQUATE	>6.5CM	>12.5CM	31	6.4	3	2.5
97	1201457	A	02/11/21	35 MIN	45Y/F	155	70	II	II	29.1	ADEQUATE	>6.5CM	>12.5CM	36	6.7	3.1	3
98	905272	B	08/11/21	90 MIN	35Y/F	160	68	I	II	26.6	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
99	1204686	B	18/11/21	50 MIN	50Y/F	157	60	III	I	24.3	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
100	1211463	A	24/11/21	120 MIN	36Y/F	152	75	III	II	32.5	ADEQUATE	>6.5CM	>12.5CM	37	6.7	3.2	3
101	401568	B	24/11/21	90 MIN	40Y/F	164	63	III	II	23.4	ADEQUATE	>6.5CM	>12.5CM	32	-	-	4
102	276682	B	24/11/21	45 MIN	52Y/F	164	86	III	I	31.2	RESTRICTED	>6.5CM	>12.5CM	36	-	-	5
103	1212996	B	25/11/21	70 MIN	44Y/F	157	66	III	III	26	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
104	1198052	A	25/11/21	25 MIN	51Y/F	156	57	III	I	23.4	ADEQUATE	>6.5CM	>12.5CM	32	6.6	3.1	3
105	1081841	A	25/11/21	40 MIN	55Y/F	162	66	II	I	25.1	ADEQUATE	>6.5CM	>12.5CM	33	6.7	3.1	3
106	1213040	B	25/11/21	100 MIN	72Y/M	166	75	III	III	27.2	RESTRICTED	>6.5CM	>12.5CM	35	-	-	5
107	1214669	B	28/11/21	120 MIN	48Y/F	163	60	II	I	22.6	ADEQUATE	>6.5CM	>12.5CM	31	-	-	4
108	1155939	A	29/11/21	40 MIN	23Y/M	157	49	II	I	19.9	ADEQUATE	>6.5CM	>12.5CM	27	6.7	3	3
109	793805	B	29/11/21	20 MIN	30Y/F	161	70	II	III	27	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
110	1232800	B	04/01/22	40 MIN	35Y/F	153	60	III	II	25.6	ADEQUATE	>6.5CM	>12.5CM	33	-	-	4
111	600138	A	05/01/22	50 MIN	28Y/F	154	48	I	I	20.2	ADEQUATE	>6.5CM	>12.5CM	28	5.9	3	2.5
112	1234902	A	06/01/22	30 MIN	41Y/F	156	84	I	II	34.5	ADEQUATE	>6.5CM	>12.5CM	39	6.8	3.3	3
113	578104	B	06/01/22	25 MIN	38Y/F	159	45	I	I	17.8	ADEQUATE	>6.5CM	>12.5CM	26	-	-	3
114	1249343	A	05/02/22	70 MIN	24Y/M	170	60	II	I	20.8	ADEQUATE	>6.5CM	>12.5CM	30	7.2	3.4	3
115	1216956	A	05/02/22	30 MIN	32Y/F	158	61	II	I	24.4	ADEQUATE	>6.5CM	>12.5CM	32	6.7	3.1	3
116	1249077	B	05/02/22	40 MIN	31Y/F	158	54	I	I	21.6	ADEQUATE	>6.5CM	>12.5CM	30	-	-	4
117	1252504	A	13/02/22	100 MIN	43Y/M	177	72	II	II	23	ADEQUATE	>6.5CM	>12.5CM	34	7.2	3.5	3
118	1248801	B	18/02/22	45 MIN	28Y/F	158	69	I	I	27.6	ADEQUATE	>6.5CM	>12.5CM	34	-	-	4
119	1258130	A	27/02/22	130 MIN	47Y/F	159	77	I	II	30.5	ADEQUATE	>6.5CM	>12.5CM	36	6.7	3.2	3
120	1254757	A	08/03/22	30 MIN	29Y/F	155	45	I	I	18.7	ADEQUATE	>6.5CM	>12.5CM	27	5.9	3	2.5

Sr NO	MRD Number	HR(/min)		SBP(mmHg)		DBP(mmHg)		SpO2		ETCO2	Expired Tidal Volume	Peak Pressure	Plateau Pressure	Visible chest rise	Bilaterally equal chest auscultation	Appearance of a square waveform EtCO2
		Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device	Baseline	After successful placement of the device							
83	1325523	62	68	108	118	64	70	99%	99%	30	460	16	14	Y	Y	Y
84	1326981	76	80	110	116	70	74	98%	99%	31	420	17	15	Y	Y	Y
85	1328083	80	92	120	108	80	72	98%	99%	31	420	12	11	Y	Y	Y
86	413751	120	116	118	120	80	74	98%	99%	33	480	22	20	Y	Y	Y
87	1327498	92	90	140	128	80	76	94%	97%	33	420	22	21	Y	Y	Y
88	1330386	112	110	130	116	70	70	98%	99%	34	480	16	15	N	N	N
89	1139609	112	104	120	112	68	74	96%	99%	34	440	14	13	Y	Y	Y
90	1146332	80	88	130	118	80	72	98%	100%	30	480	16	15	Y	Y	Y
91	1129447	82	88	128	116	74	70	98%	100%	32	450	18	16	Y	Y	Y
92	1133270	98	104	110	106	78	72	94%	98%	34	460	21	19	N	N	N
93	952978	88	96	126	120	70	74	98%	100%	33	500	20	18	Y	Y	Y
94	1136161	68	78	108	102	64	68	99%	100%	32	450	14	13	Y	Y	Y
95	1170016	68	74	116	108	74	70	98%	100%	33	450	10	8	Y	Y	Y
96	1184655	88	82	122	118	68	70	97%	99%	32	400	18	16	Y	Y	Y
97	1201457	106	98	114	110	78	72	99%	100%	33	400	15	14	Y	Y	Y
98	905272	76	86	122	116	70	74	100%	100%	30	440	12	11	Y	Y	Y
99	1204686	78	86	110	104	66	70	96%	99%	35	380	15	14	Y	Y	Y
100	1211463	98	90	110	114	74	72	98%	99%	32	400	16	14	Y	Y	Y
101	401568	76	88	124	108	86	74	99%	100%	33	460	20	18	Y	Y	Y
102	276682	88	98	150	138	90	94	97%	99%	33	420	20	18	N	N	N
103	1212996	82	94	130	122	90	74	96%	99%	34	420	21	18	Y	Y	Y
104	1198052	68	76	120	114	70	74	99%	100%	34	420	19	18	Y	Y	Y
105	1081841	90	96	110	102	70	64	98%	99%	33	400	20	19	Y	Y	Y
106	1213040	62	74	118	108	84	78	95%	97%	36	450	13	11	Y	Y	Y
107	1214669	60	76	124	112	68	70	95%	98%	34	450	19	18	Y	Y	Y
108	1155939	88	82	110	114	74	70	99%	100%	31	420	18	16	Y	Y	Y
109	793805	86	98	110	102	70	64	99%	100%	33	440	15	13	Y	Y	Y
110	1232800	92	86	100	106	60	70	98%	99%	35	420	16	15	Y	Y	Y
111	600138	80	86	114	108	62	68	98%	100%	32	440	14	12	Y	Y	Y
112	1234902	92	86	140	128	80	74	96%	99%	31	450	18	16	Y	Y	Y
113	578104	80	96	110	106	72	68	97%	100%	30	440	20	17	Y	Y	Y
114	1249343	72	84	120	112	78	60	97%	99%	32	460	15	14	Y	Y	Y
115	1216956	98	90	108	100	70	68	99%	100%	34	420	13	11	Y	Y	Y
116	1249077	88	96	110	106	70	68	100%	100%	32	440	21	20	Y	Y	Y
117	1252504	84	80	140	128	80	72	98%	100%	30	450	11	10	Y	Y	Y
118	1248801	86	92	120	112	84	74	98%	99%	32	430	12	10	Y	Y	Y
119	1258130	86	80	130	124	70	66	97%	99%	30	450	13	12	Y	Y	Y
120	1254757	80	88	100	104	70	62	100%	100%	35	400	20	17	Y	Y	Y

Sr NO	MRD Number	Oral leak pressure >10cm H_2O	Successful placement	Successful placement in first attempt	Insertion attempts	Insertion time	Any change in the size of device required If yes, size of the device	Difficulty of insertion	Desaturation episodes	Dental injury	Blood staining	Dysphagia	Dysphonia	Sore throat rating scale
83	1325523	24	Y	Y	1	13	**N**	EASY	N	N	N	N	N	3
84	1326981	23	Y	Y	1	12	**N**	EASY	N	N	N	N	N	1
85	1328083	24	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
86	413751	29	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	4
87	1327498	22	Y	Y	1	13	**N**	EASY	N	N	N	N	N	2
88	1330386	29	N	N	2	21	**Y/4**	MODERATE	N	N	Y	N	N	3
89	1139609	28	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
90	1146332	24	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
91	1129447	27	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	2
92	1133270	32	N	N	2	23	**Y/4**	MODERATE	N	N	Y	N	N	5
93	952978	32	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	4
94	1136161	29	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	2
95	1170016	30	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	2
96	1184655	24	Y	Y	1	14	**N**	EASY	N	N	N	N	N	1
97	1201457	25	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
98	905272	31	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
99	1204686	30	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	4
100	1211463	26	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
101	401568	32	Y	Y	1	17	**N**	MODERATE	N	N	N	N	N	4
102	276682	32	N	N	2	23	**Y/4**	MODERATE	N	N	Y	N	N	5
103	1212996	32	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
104	1198052	27	Y	Y	1	14	**N**	MODERATE	N	N	N	N	N	3
105	1081841	28	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	2
106	1213040	32	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	4
107	1214669	31	Y	Y	1	17	**N**	MODERATE	N	N	N	N	N	4
108	1155939	30	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
109	793805	30	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	4
110	1232800	31	Y	Y	1	17	**N**	MODERATE	N	N	N	N	N	4
111	600138	22	Y	Y	1	15	**N**	EASY	N	N	N	N	N	1
112	1234902	23	Y	Y	1	15	**N**	EASY	N	N	N	N	N	1
113	578104	32	Y	Y	1	16	**N**	MODERATE	N	N	N	N	N	3
114	1249343	28	Y	Y	1	15	**N**	MODERATE	N	N	N	N	N	3
115	1216956	23	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
116	1249077	32	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	4
117	1252504	22	Y	Y	1	15	**N**	EASY	N	N	N	N	N	2
118	1248801	30	Y	Y	1	17	**N**	MODERATE	N	N	Y	N	N	4
119	1258130	23	Y	Y	1	14	**N**	EASY	N	N	N	N	N	2
120	1254757	24	Y	Y	1	15	**N**	EASY	N	N	N	N	N	1

No. BFUHS/2K21/ [illegible]

Dated: [illegible]

The Principal
DMC, Ludhiana

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Akshita Khanna**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis

A study comparing two methods for selection of optimal size of auragain laryngeal mask airway in adults.

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Co-Supervisor

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2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

DOCTOR OF MEDICINE

In

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

March 2021

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ABSTRACT OF PLAN OF THESIS

Title	A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS
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Introduction: Auragain laryngeal mask airway (LMA) has been used in patients for short to medium duration surgical procedures and has been proved to be beneficial. Appropriate size selection of the LMA has contributed to its successful placement in the first attempt, thereby avoiding multiple episodes of desaturation and other associated respiratory or hemodynamic complications. We hypothesize that the auricle size based method of size determination of LMA would be better in comparison to the weight based method.

Aim of Study: To compare the successful placement of LMA in the first attempt using auricle size based method and weight based method in adult population.

Materials & methods: A prospective, randomized, interventional trial will be conducted on 120 ASA I, II and III adult patients undergoing surgical procedures under general anaesthesia who will be divided into 2 groups. In group A, Auragain LMA size will be selected based on the size of the auricle of the patient while in group B, Auragain LMA size will be selected based on weight of the patient. Successful placement of Auragain LMA, time taken for insertion, number of attempts for successful insertion, intra-operative and post-operative complications will be studied. Data collected will be statistically analysed.

Clinical Significance: Adequate size of LMA selection can influence successful placement of Auragain LMA in adults thereby creating a safety net in terms of reduced episodes of desaturation, decreased air leak, thus establishing its use as a sole airway device in short to medium duration surgical procedures.

Keywords: Auragain LMA, Weight, Auricle size, Oral leak pressure

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CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS"** exist in the Department of Anaesthesiology at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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4	DATE OF ADMISSION OF COURSE	26 July 2020
5	TITLE OF THE TOPIC	A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Laryngeal mask airways are being commonly used for airway management not only in the operating room but also in the emergency care settings. They play an important role in maintaining ventilation and providing oxygenation to the patients.[1] The Ambu Auragain, a second generation laryngeal mask airway, is used for both ventilation as well as a conduit for tracheal intubation. It has its original anatomical curve which helps in rapid placement. It also has a thin and soft cuff which helps in providing a good seal thus preventing gastric regurgitation and aspiration.[2]

Selection of proper size of LMA is important for its safe and effective use. The weight based technique, which is the gold standard method is not always accurate. The size of the airway anatomy does not relate linearly to the body weight such as in obese and malnourished patients. These factors may lead to inappropriate size selection which may result in larger size LMA causing trauma to the airway and a smaller one causing inadequate ventilation.[3]

To overcome these concerns various alternatives to weight based technique have been tried by researchers. Gallart et al proposed 3 finger sizing method to determine the size of LMA after conducting a study on 183 children.[3] Zahoor et al in 2012 studied the use of external ear as a surrogate marker to determine the correct size of LMA in 210 pediatric patients.[4] They found the ear size based method to be comparable to that of weight based method. Both the above studies were restricted only to pediatric population. There have been very limited studies to determine the accurate size of LMA in adult population.

Since the shape and size of the auricle corresponds to that of the LMA, we tend to compare the auricle size based technique to weight based technique for selection of appropriate size LMA in adult population.

6.2 REVIEW OF LITERATURE

Supraglottic airway devices (SADs) are widely used for airway management during general anaesthesia. These devices provide a seal around laryngeal inlet and are used as an alternative to tracheal intubation in maintaining upper airway and permitting mechanical ventilation.[5]

Laryngeal mask airway (LMA) helps improve haemodynamic and respiratory stability of the patients, better mucociliary clearance with reduced need for anaesthetics. It reduces the risk of traumatisation of glottic structures. It lowers the incidence of post operative complications such as laryngospasm, hoarseness, sore throat and nausea as compared to the use of an endotracheal tube(ETT).[6,7] Zoremba M et al have also compared endotracheal intubation with SAD on parameters like leak pressure, ease of intubation and urgency to secure airway. They concluded that SAD can be used as an alternative to endotracheal intubation.[8]

The Ambu Auragain LMA, a second generation SAD, is anatomically curved to follow the human airway and provide high seal pressures. It has gastric access, bite block and wider airway tube which provides an intubation conduit. Reesha Joshi et al also conducted a study in 94 children comparing Ambu Auragain and LMA Proseal and observed that the ease and success rate for device placement, fibreoptic visualisation of larynx and the complications were comparable. However the time of insertion was shorter and mean oropharyngeal seal pressure was higher in Ambu Auragain than in LMA Proseal group. Thus they concluded that Ambu Auragain could become a useful alternative to LMA Proseal for securing airway in children.[2] Lukas Gasteiger et al conducted a study in 57 patients comparing the Ambu Aura-I and Ambu Auragain laryngeal mask. They concluded that Ambu Auragain served as a reliable device for FOB-guided tracheal intubation as first attempt device insertion was successful in all the patients with Auragain as compared to 97% with Aura-I.[9]

Optimal size selection is critical to the safe and effective use of the laryngeal mask airway. Ideally the optimal size LMA should be easy to insert, have an oropharyngeal leak pressure sufficient for positive pressure ventilation, a pharyngeal mucosal pressure less than capillary perfusion pressure and be positioned such that instruments pass easily into the respiratory tract.[10] In order to select LMA of appropriate size for its safe and effective use, various studies have been conducted. These studies concluded that selection of size of LMA is based upon various factors namely sex of the patient, body weight, upper airway geometry and anatomical features. A.S. Rao et al conducted a study in 2003 to determine optimal size of LMA in 135 Malaysian female aduts. They compared LMAs of 3, 4, 5 sizes. Optimisation of size of LMA was based on 4 parameters: oropharyngeal leak pressure, fibreoptic score, no. of attempts at placement and percentage of vocal cord seen. They concluded that LMA of size 4 was optimal for use in Malaysian adult females.[11] Asai et al conducted a study in 1998 to compare size 3 and size 4 laryngeal mask in females and size 4 and size 5 in males for success rate of insertion, incidence of airleak and pressure exerted on pharynx. They found that sizes 4 and 5 were superior to sizes 3 and 4 for females and males respectively and did not produce higher pressures on the pharyngeal mucosa.[12] Berry et al conducted a study in 2002 in 30 apnoeic anaesthetised adults weighing <100kg and size 3, 4, 5 were inserted in each patient in random order and they found that size 5 LMA was optimal in 63% of adult patients, size 4 in 37% and size 3 was never optimal.[13]

In clinical practice, the most commonly used method for size determination is weight based method. However it is not suitable in many patients due to wide range for each category of weight, variation in size and individual anatomy and for overweight or underweight as it is based on actual body weight rather than ideal body weight. H. J. Kim et al compared conventional laryngeal mask airway sizing according to actual weight and ideal weight in over- and underweight children and concluded that in overweight children LMA size based on patients'

weight is appropriate while in underweight children, LMA size by an ideal weight is better.[14] Syafri Kamsul Arif et al also compared actual and ideal body weight for size selection of I-Gel LMA in 22 obese patients. A significant higher first attempt insertion rate, shorter insertion time and easier placement was observed in ideal body weight group and they concluded that ideal body weight is better for size selection of the I-Gel LMA in obese patients than the actual body weight.[15]

No similar method exists for rough estimation of the required LMA size. Thus various studies are being conducted to find an effective alternative method to the existing weight based method of size determination of LMA.

Meilin Weng et al conducted a study to compare the efficacy of LMA supreme placement when the size was determined by thyromental distance as compared to by body weight. So 80 patients were enrolled in the study and randomly allocated into 2 groups. In thyromental distance based group, most used LMA was size 4 followed by size 3. Whereas in weight based group, most commonly used was size 4 followed by size 5. They concluded that thyromental distance based method is better as compared to weight based method in terms of guaranteeing better ventilation, easier device placement and a reliable pharyngeal seal.[16]

Yi-Hsuan Huang et al conducted a study on 21 male patients for selection of optimal size of LMA based on tongue width method. The LMA would be selected with the widest width of each LMA corresponding to the same width as that of the tongue of the patient. Frequency of insertion attempts, presence of cuff in the mouth, end tidal CO_2 shown on monitor, oropharyngeal leak pressure and fibreoptic score were measured following each LMA insertion. The authors concluded that tongue width based method is a convenient and efficacious alternative to weight based method for selecting optimal size LMA.[17]

Gallart et al compared the traditional weight based method for estimation of size of LMA with a method using combined width of patient's index, middle and ring fingers. They found agreement between both the methods with disagreement of only one size in 22% of cases.[18]

Zahoor et al in 2012 studied 210 pediatric patients aged 6 months to 15 years to determine if the size of external ear, which also resembles the shape of the LMA, could act as a proxy for finding the adequate size of LMA. They found the success rate to be 93.3% in terms of insertion in first attempt and being able to achieve adequate ventilation. The author thus concluded that auricular size could be used as an additive method to the existing standard methods.[19]

Murat Haliloglu et al conducted a study in 2017 for determining the size of ProSeal LMA in 197 children. The correct size was determined according to the size of the auricle in children and the results were compared with the standard weight based method. Insertion and adequate ventilation was recorded in 185 patients in the first attempt and 12 required a second attempt and they concluded that the auricle based method for determining the size of ProSeal LMA is useful compared with the manufacturer's weight based formula.[20]

Uma Kamath et al in 2019 compared pinna size based method to weight based method in 100 pediatric patients under the age of 15 years. Parameters such as number of attempts and change of the size of LMA were monitored. They concluded that pinna size based estimation for determining the size of LMA is a convenient and feasible alternative to traditional weight based estimation.[21]

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the successful placement of LMA in the first attempt using auricle size based method and weight based method in adult population.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA:

The study will be conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval from the hospital ethics committee. A written informed consent will be obtained from all patients selected for study.

METHOD OF COLLECTION OF DATA:

A prospective, randomised, interventional study will be conducted on ASA I, II and III adults. A total of 120 patients will be recruited in the study and an equal number will be randomised using computer generated random numbers contained in sealed, sequentially numbered envelopes, which shall be opened by an independent anaesthesiologist.

Inclusion criteria: Healthy individuals of age more than 18 years with American Society of Anaesthesiologists' (ASA) physical status I, II and III, scheduled for elective surgery in supine position.

Exclusion criteria:

- Age <18 years
- BMI >35kg/m^2
- High risk of regurgitation or aspiration
- Limited mouth opening
- Infections or pathological abnormality of oral cavity or pharynx
- Patients with h/o hiatus hernia or gastroperesis
- Pregnancy
- Structural ear deformity

Group Allocation - A written informed consent will be obtained from all the patients. Patients will be divided into 2 groups of 60 patients each.

Group (A): Auragain LMA size will be selected based upon the size of the auricle of the patient.

Group (B): Auragain LMA size will be selected based upon weight of the patient.

Anaesthesia technique - All patients will be subjected to routine pre-operative assessment and standard fasting protocols.

An appropriate size Auragain LMA will be selected using the technique randomly allocated to that particular patient. Auragain LMA size in group (A) will be selected by measuring the size of the auricle with a ruler in the vertical and horizontal dimensions in cms. Vertical ear length will be measured from the most dependent portion of the lobule to the furthest portion of the auricle. Horizontal ear length will be measured from the tragus to the furthest part of the helix horizontally.

	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5
Vertical(cm)	6.5	8	9	10
Horizontal(cm)	4	5.5	5.75	6.25

The size of LMA to be used will be based on the above dimensions. The nearest corresponding size of partially inflated LMA will be chosen and inserted after induction. If the auricle size fell between two sizes of Aura LMA, the larger size will be considered. LMA one size larger and one size smaller will be available for exchange if the approximation was incorrect. The size of LMA in group (B) is based on patient's weight as per the manufacturer's guidelines (20-30kg – size 2.5, 30-50 kg - size 3, 50-70 kg - size 4, >70 kg - size 5).[2,5]

In the operating room, all patients will be positioned in supine position with 10cm pillow underneath head. Monitors will be attached in the form of pulse oximeter, non invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$) and 5 lead electrocardiography (ECG). Intravenous access will be secured. Premedication will be given in the form of intravenous injections of midazolam 0.02 mg/kg, metoclopramide 10 mg and glycopyrrolate 0.2 mg. Fentanyl would be used for intraoperative analgesia in the dose of 2mcg/kg intravenous. After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical face mask, anaesthesia will be induced with 1% propofol 2-2.5 mg/kg titrated to loss of verbal response. Neuromuscular blockade will be achieved by intravenous injection of atracurium 0.5 mg/kg. After achieving adequate jaw

relaxation, the head is placed in sniffing position. The selected Auragain LMA cuff would be lubricated with a water based jelly and inserted. Anesthesiologists having a minimum of one year experience with supraglottic devices and having inserted more than 50 of them will be involved in the study. An independent observer will note the time of insertion of LMA. After insertion, the cuff was inflated with air to a pressure of 60cm of H_2O using a cuff manometer. The lungs will be mechanically ventilated using volume controlled ventilation set to deliver a tidal volume of 8ml/kg, respiratory rate to maintain $EtCO_2$ between 30 and 40 mmHg, inspiratory and expiratory ratio of 1:2 and a positive end-expiratory pressure of 5 cm of water. Initial assessment of ventilation is performed by observing the square wave capnograph and chest rise. Oropharyngeal leak pressure(OLP) is measured by adjusting the fresh gas flow to 3L/min and closing the adjustable pressure limiting valve of the circle system, the minimum airway pressure at which audible gas leak starts to occur as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures will not be allowed to exceed 40 cm of H2O.[22] The total fresh gas flow will be maintained at 3 L/min. Anaesthesia will be maintained using isoflurane 1-2% in 50:50 oxygen and air. A nasogastric tube of appropriate size will be passed through the gastric tube channel in all the cases. In case of failed passage of LMA into the pharynx or ineffective ventilation (expiratory TV <5mg/kg) or absence of a capnography tracing, the LMA would be removed and a smaller or a larger size will be attempted respectively. If successful insertion could not be achieved even after second attempt, endotracheal intubation would be done and this would be regarded as a failure of insertion of supraglottic device. At the end of the procedure after confirming the return of spontaneous ventilation, neuromuscular blockade will be reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.006 mg/kg and LMA will be removed once the patient gains consciousness. Patients will then be shifted to post-anaesthesia care unit for observation.

Observations:

PRIMARY OUTCOME:

First attempt success rate - The number of patients with successful insertion of LMA in the first attempt. It will be confirmed by observing visible chest rise, bilateral chest auscultation, appearance of a square wave end-tidal carbon dioxide waveform and oral leak pressure(OLP).

SECONDARY OUTCOMES:

Number of attempts – Number of attempts needed for successful placement will be recorded. A maximum of two attempts will be allowed.

Insertion time of Aura LMA - The insertion time will be defined as the duration from when the anaesthesiologist picks up the LMA till the capnography tracing is obtained.

Difficulty of insertion – The anaesthesiologist inserting the device will provide a subjective assessment of the insertion procedure by grading it as easy=1, moderate=2, difficult=3 and impossible=4.

Insertion failure – If we are unable to place the LMA successfully even after 2 attempts, it will be considered as failure to insert.

Respiratory Parameters – Expired Tidal Volume, Peak Pressure, Plateau Pressure and $EtCO_2$ will be recorded.

Adverse events – At the time of removal of Auragain LMA, any staining of the LMA with blood will be noted.

Number of episodes of desaturation i.e., SpO_2 < 90% will be noted down, the patients will be mask ventilated with 100% oxygen till optimal SpO_2 level is reached (95%).

Dental injury if any will be noted down.

Patients will be followed up for 12 hours after the surgery for complaints of sore throat, dysphagia and dysphonia.

Sore throat will be rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up in post anaesthesia care unit. A score of more than 4 on NRS will be considered as sore throat.[23]

Statistical Analysis:

Data will be described in terms of range; median (inter quartile range IQR), mean ± standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using ANOVA. For comparing categorical data, Chi square ($\chi 2$) test will be performed and Fischer exact test will be used when the expected frequency is less than 5.A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

Sample size calculation:

The alpha level used for this analysis was $p<0.05$ and beta was 0.20. Sample size was estimated from the results of previous study using requirement of changing LMA as the parameter, which is the primary outcome of our study.[21] Our sample size came out to be 60 subjects per group at power of 0.99 and with an effect size of 1 with 10% chance of error with $\alpha = 0.05$, $\beta = 0.20$ and confidence interval of 95%.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached alongwith.

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DEPARTMENT OF ANAESTHESIOLOGY

DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA

PROFORMA

Sr. Number: Group: Technique of size selection:

MRD Number: Date of surgery:

Duration of surgery:

DEMOGRAPHIC DATA

Age and Sex: ASA grade:

Height (cm): Nutritional status:

Weight (kg): BMI:

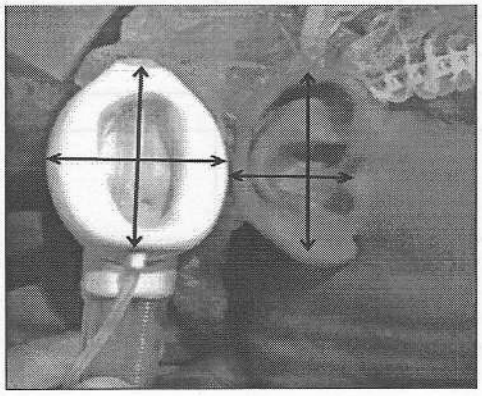
Mallampati score: Range of neck movement:

Edentulous: Thyromental distance:

Maximal interdental distance: Neck circumference:

Overbite test: Sternomental distance:

AURICLE DIMENSIONS



VERTICAL (cm):

HORIZONTAL (cm):

SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

SIZE OF AURA LMA INSERTED

	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5
Vertical(cm)	6.5	8	9	10
Horizontal(cm)	4	5.5	5.75	6.25

HAEMODYNAMIC PARAMETERS

Vitals	HR (/min)	SBP (mmHg)	DBP (mmHg)	Mean BP(mmHg)	SPO_2 (%)
Baseline					
Induction					
1 min					
2 min					
3 min					
4 min					
5 min					
Till successful placement of the device					
After successful placement of the device					

RESPIRATORY PARAMETERS

Vitals	Expired Tidal Volume	Peak Pressure	Plateau Pressure	$EtCO_2$ (mmHg)
Baseline				
Induction				
1 min				
2 min				
3 min				
4 min				
5 min				
Till successful placement of the device				
After successful placement of the device				

SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

CRITERIA FOR SUCCESSFUL PLACEMENT

Parameter		YES	NO
Visible chest rise			
Bilaterally equal chest auscultation			
Appearance of a square waveform $EtCO_2$			
Oral leak pressure >10mm Hg	_____mm Hg		

Successful placement: Yes/No

Successful placement in first attempt: Yes/No

Insertion attempts:

Insertion time:

Any change in the size of device required: YES / NO

If yes, Size of the device:

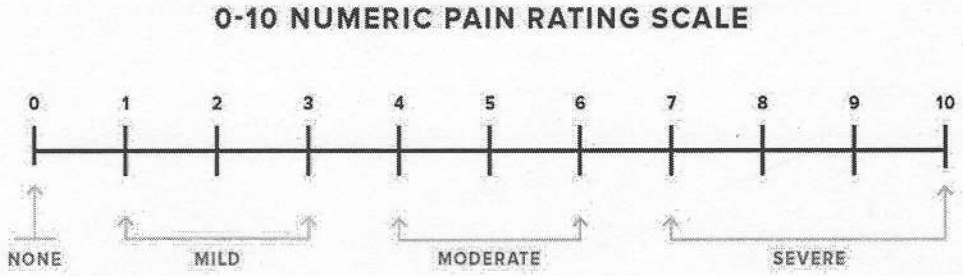
DIFFICULTY OF INSERTION .

1) Easy	2) moderate	3) difficult	4) impossible

COMPLICATIONS

		YES	NO
Desaturation episodes (SpO_2 less than 90%)	Number of episodes: ____		
Dental injury			
Blood staining			
Dysphagia			
Dysphonia			

SORE THROAT



SIGNATURE OF CANDIDATE SIGNATURE OF SUPERVISOR

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... .....am willing to participate in the study **"A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Supervisor **Signature of Candidate**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____ निवासी _____ इस शोधकार्य **"A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____ਵਾਸੀ

_____

"A STUDY COMPARING TWO METHODS FOR SELECTION OF OPTIMAL SIZE OF AURAGAIN LARYNGEAL MASK AIRWAY IN ADULTS" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ